

EPA Registration 2517-134 Vol. 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 20, 2015

Mr. Kelly R. Hoskins
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-1710

Subject: Notice of Extension of Conditional Registration until September 11, 2017
Product Name: Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Registration Number: 2517-134
Application Date: June 30, 2015
Decision Number: 506490

Dear Mr. Hoskins:

This letter is in reference to your request to extend the conditional, time-limited registration for the above-referenced registration. The above-referenced registration contains conditions calling for the registration to expire after two years. Additionally, your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information for the above-referenced registration.

The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is therefore granting the request to extend the two-year time-limited registration restriction. As such, the following change is being made to the terms and conditions for the product listed above:

- The two-year time-limited registration restriction has been extended. The new expiration date for the registration listed above is September 11, 2017.

Please note that the product is still subject to all other previously required conditions of registration. If your company wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for the product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you remember, the Agency included this time limitation as a condition of registration for your product to allow for the post-market surveillance¹ of the product. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g., tables, charts, information on stewardship activities, etc.):

- A summary and analysis of the incidents received associated with the product, including information on the following:

¹ <http://www.epa.gov/pesticides/health/spot-on-meetings.html>

- A comprehensive analysis of incident rates per doses distributed;
 - An analysis of historical incident trends since the products' release into the marketplace;
 - An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If the product is also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day fast-track submissions, as the Agency requires time to fully evaluate the information provided. After receiving these submissions, the Agency will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

If you have any questions, please contact me by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, loopy oval shape.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

June 30, 2015

Kable Bo Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

**Subject: Two-Year Extension of Time Limited Registration for
 Sergeant's Fipronil + Methoprene Squeeze-On for Dogs,
 EPA Reg. No. 2517-134
 Sergeant's Fipronil + S-Methoprene Spot-On for Cats,
 EPA Reg. No. 2517-135
 Sergeant's Fipronil Squeeze-On for Dogs,
 EPA Reg. No. 2517-136
 Sergeant's Firponil Spot-On for Cats,
 EPA Reg. No. 2517-137**

Dear Mr. Davis:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting a request to have the two-year time limited registrations for the subject end use products extended for an additional two years (i.e. until September 11, 2017).

The time-limited registrations for the subject products were extended two years from the date of EPA stamped letter/label dated September 11, 2013 (revised expiration date September 11, 2015).

By formally requesting extensions, Sergeant's would like to ensure that time-limited registrations be extended for two years, so that the registrations are renewed in a timely manner with uninterrupted product registration.

If you have any questions, please contact me at 402-938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Manager of Regulatory Affairs

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <h1 style="margin: 0;">EPA</h1> <p>United States Environmental Protection Agency Washington, DC 20460</p> </div> <div style="text-align: right;"> <input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other </div> </div>	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 2517-134	2. EPA Product Manager Kable Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Fipronil + Methoprene Squeeze-On for Dogs	5. PM # 3	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-1710 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Request to extend the two-year time-limited registration. Please see cover letter for details.**Section III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. _____	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. _____	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
*Certification must be submitted		No. per Container _____	No. per Container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly R. Hoskins	Title Manager of Regulatory Affairs	Telephone No. (Include Area Code) 402-938-7079
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>	3. Title Manager of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins	5. Date: 6/30/2015	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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AND POLLUTION PREVENTION

July 20, 2015

Mr. Kelly R. Hoskins
Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-1710

Subject: Label Amendment – Adding an optional minimum 5 lb. weight; adding marketing claims; clarifying application directions
Product Name: Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Registration Number: 2517-134
Application Date: February 18, 2015
Decision Number: 500304

Dear Mr. Hoskins:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

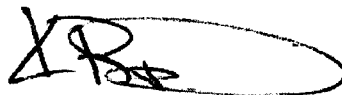
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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Decision No. 500304

with FIFRA section 6. If you have any questions, please contact me by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Sergeant's Master Label

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL + METHOPRENE

{Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.}

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs:]

[Sergeant's® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sergeant's® Ectoadvance Plus (Spot On) for Dogs]

[Sergeant's® AdvanSpot Plus (Spot On) for Dogs]

[Sergeant's® PRONYL OTC™ PLUS for Dogs]

[SentryProline Plus (Spot On) for Dogs]

[SENTRY® FIPROGUARD™ PLUS for Dogs]

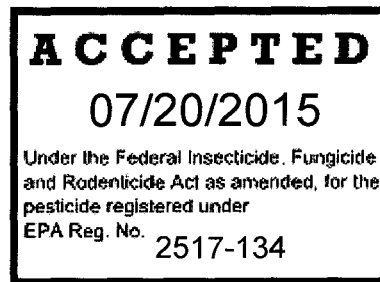
[SENTRY® AdvanSpot Plus (Spot On) for Dogs]

[Sentry® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sentry® Ectoadvance Plus (Spot On) for Dogs]

[PetArmor® Plus for dogs]

[Sergeant's® PetArmor® Plus for dogs]



[1.5cm x 1.5cm on final or as indicated]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR}

For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age {OR}

For use ONLY on dogs [[&][and] puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR}

ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] {OR}

ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-][to] 22 lbs {OR}

ONLY For Dogs & Puppies 8 weeks or older [&][and] 5[-][to] 22 lbs

{box only designates Vet Only language}

{**SUBLABEL:** FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION}

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels.

Not for residential use. Do not repackage.

[Ideal for shelter use when under direct supervision of veterinarian]

[Professional Roll Pack]

[Convenient roll pack for in clinic use]

[Convenient roll pack for animal facility use]

[For use only by licensed veterinarians]

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[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]

[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [Brand Name][This product] monthly to break the flea life cycle.]

[Use [Brand Name][This product] monthly to control ticks and chewing lice]

[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]

[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]

[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]

[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]

[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]

[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]

[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]

[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks],][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]

[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

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[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]

[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]

[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]

[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]

[With (S)-methoprene to Break Flea Life Cycle]

[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]

[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]

[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]

[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Prevents all stages of the flea life cycle from developing]

[Controls reinfestation of fleas for up to 3 months]

[Effective against all stages of the flea life cycle]

[Effectively controls all stages of the flea life cycle]

[All Others]

[For Dogs and Puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [4-22 lbs.], [5-22 lbs], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]

[Fast Acting] [Long Lasting]

[Convenient spot treatment]

[Easy to Use [Application]]

[Best if used year round!]

[For year-round protection, apply [Brand Name] monthly]

[(ICON Showing [4 week] [1 month] [30 day] Protection)]

[Apply monthly]

[Prevents reinfestation of listed pests for [4 weeks] [1 month]]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]

[Controls mites that may cause sarcoptic mange]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]

[[Free] Calendar Stickers Inside!]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]

[Fipronil (9.8%) + (S)-methoprene (8.8%)]

[Contains the same active ingredient(s) used in [FRONTLINE® Plus for Dogs (or any approved ABN)].*]]

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[Compare to [FRONTLINE® Plus for Dogs (or any approved ABN)], contains the same active ingredients.*]
[Compare to [FRONTLINE® Plus for Dogs (or any approved ABN)], contains the same active ingredients
fipronil and (S)-Methoprene.*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, the same active ingredients
used in [FRONTLINE® Plus for Dogs (or any approved ABN)].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to the same active
ingredient(s) used in [FRONTLINE® Plus for Dogs (or any approved ABN)].*]
[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers
of [FRONTLINE® Plus for Dogs (or any approved ABN)].]
[[Brand Name][This product][Frontline®] is a registered trademark of [Merial®] [Company name].]
[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]
[[1][2][3][4][5][6][12][24] Applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]]
[Stops existing infestation and prevents establishment of additional infestation of listed pests]
[Lift [here] for more information]
[S][Small][4-22 lbs.][5-22 lbs][M][Medium][23-44 lbs.][L][Large][45-88 lbs.][XL][Extra Large][89-132 lbs.]
[Direct to skin [tube][vial][applicator][pipette]]
[Easy to Use] [tube][vial][applicator][pipette]]
[Clean cut [open] [tube][vial][applicator][pipette]]
[No-mess [open] [tube][vial][applicator][pipette]]
[Clip-tip design [tube][vial][applicator][pipette][!]]
[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]
[Save Now!]
[Value Size]
[Club Size]
[Bonus Size]
[Club Pack]
[Great Value]
[Better Value]
[Bonus Pack]
[(x) + (x) bonus pack!]
[Buy more and save!]
[Buy X Get Y Free]
[Buy 3 get 1 free]
[(x)% (More) (Free)!]
[33% more free]
[(x) Dose(s) Free!]
[(x) Day(s) (Free)!]
[(x) Month(s) Free!]
[(x) Day(s) of treatment- Free!]
[(x) Tube(s) Free!]
[(x) Applicator(s) Free!]
[(x) Application(s) Free!]

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ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-methoprene.....	8.80%
OTHER INGREDIENT:	<u>81.40%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Insert] [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) [applicators][tubes][vials][pipettes]]
[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

OR {box only designates Vet Only language}

Net Contents: X fl oz X count [Y – X fl oz [tube][vial][applicator][pipette][s]] [Thirty-five] 35[Fifty][50][Seventy-five][75][One hundred][100] [One hundred sixty 160]
--

[0.023 fl oz (0.67 mL)] [0.045 fl oz (1.34 mL)] [0.091 fl oz (2.68 mL)] [0.136 fl oz (4.02 mL)]
[applicators][tubes][vials][pipettes]

{END - FRONT PANEL}

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BACK / SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[[Brand Name]][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name]][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

OR {box only designates Vet Only language}

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

FIRST AID	
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs.

Sergeant's Master Label

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Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4 (or 5)][23][45][89] lbs. Use entire contents of [tube] [vial] [applicator] [pipette] on each dog. [Do not split one [tube] [vial] [applicator] [pipette] between dogs.] Do not use multiple [tube] [vial] [applicator] [pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert [tube] [vial] [applicator] [pipette] over dog and use open end to part dog's hair. Squeeze tube [vial] [applicator] [pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs. {OR} Only For Dogs Weighing 5 [-] [to] 22 lbs. Do not apply to dogs weighing less than 5 lbs. [including small dogs and puppies, 8 weeks or older]:

Apply one [tube] [vial] [applicator] [pipette] (0.67 mL)(0.023 fl oz) [directly to skin][from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs. Do not apply to dogs weighing less than 23 lbs.

Apply one [tube] [vial] [applicator] [pipette] (1.34 mL)(0.045 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs. Do not apply to dogs weighing less than 45 lbs.

Apply one [tube] [vial] [applicator] [pipette] (2.68 mL)(0.091 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

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{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not apply to dogs weighing less than 89 lbs. Do not use two tubes on dogs greater than 132 lbs. Apply one[tube] [vial] [applicator] [pipette] (4.02 mL)(0.136 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/[25°C]]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA] [U.S. Patent No. 5,567,429]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-134
EPA Est. No. [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

DOG SQUEEZE ON
FIPRONIL+METHOPRENE

{How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.}

[[Clip. Part. Squeeze.]]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea and tick protection where it needs to be.]

[Application Instructions] [Directions for Use]

How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert [tube] [vial] [applicator] [pipette] over dog and use open end to part dog's hair.
2. Squeeze [tube] [vial] [applicator] [pipette] firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh [your] dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][This Product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application date][Date of Application]

[calendar stickers with [Brand Name] [This Product]

[Place stickers on your calendar as a reminder to reapply [Brand Name] [This Product] in 30 days.]

[Place sticker on your calendar or [refrigerator] to remind yourself to apply [Brand name][this product] to your dog]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]



























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{Optional graphics below may or may not appear anywhere on finished label}

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

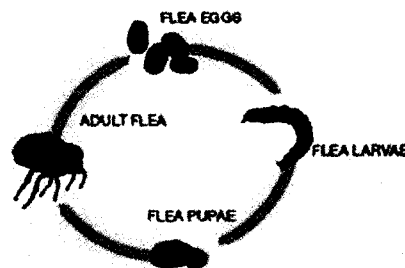


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{END - PACKAGE COPY}

[Flea life cycle diagram] [Flea Life Cycle]

TUBE/VIAL LABEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

{Front Label}

{Icon as indicated}

{Back Label}

{Brand Name} For Dogs [X-Y] lbs \geq 8 wks
fipronil 9.8%, s-methoprene 8.8%
0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)
0.136 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions
before using. Use scissors to open.
EPA REG. No. 2517-134 {label code}

{EPA REG No may be on either the front or back label}

{END - TUBE/VIAL LABEL}

Chao, Julie

From: Kelly Hoskins <Kelly.Hoskins@perrigo.com>
Sent: Friday, July 17, 2015 8:12 PM
To: Chao, Julie
Cc: Davis, Kable; IVB1
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137
Attachments: 2517-134 (RGU) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) Clean.docx; 2517-134 (RGU) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) HL.docx; 2517-135 (RGL) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) HL.docx; 2517-135 (RGL) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) Clean.docx; 2517-136 (RGA) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) HL.docx; 2517-136 (RGA) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) Clean.docx; 2517-137 (RGT) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) HL.docx; 2517-137 (RGT) V15.1b AMND 11Feb15 Submission 18Feb15 Approved (Pending) Clean.docx

Julie,
Here are the updated labels to the changes we discussed.

Please, note the change in my email address.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: kelly.hoskins@perrigo.com | sergeants.com



From: Chao, Julie [mailto:Chao.Julie@epa.gov]
Sent: Thursday, July 16, 2015 1:14 PM
To: Kelly Hoskins
Cc: Davis, Kable; IVB1
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Hi Kelly,

Just a few minor comments, marked up in the attached. For the comparative Frontline claims, it appears that you have listed either inactive or alternate brand names. We need you to use the current primary brand names for the cited products. The references to listing other ABNs should be qualified as "approved ABNs."

For the two cat products, it looks like the statements about applying the product directly to the animal's skin are optional. These should not be bracketed. Or, somewhere on the label, it should state clearly (as with the dog products), that the contents must be applied directly to the skin.

Finally, please clarify the color. _____ will be used for the cat prohibition icon. The _____ mitigation requires yellow and black. The mitigation also requires that the word "dog" be at least 75% the size of the rest of the brand name.

Sorry I wasn't able to catch you in person earlier today. Please feel free to give me a call if you want to discuss further. Otherwise, please email revised labels (highlighted AND clean).

Thanks!
Julie

From: Kelly Hoskins [mailto:Kelly.Hoskins@perrigo.com]
Sent: Friday, July 10, 2015 9:54 AM
To: Chao, Julie
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Julie,
Here are the labels, as we discussed on the phone I have removed all references to #1 Vet and associated claims due to EPA denial of use. Original submitted changes are in yellow, those in blue are the updated compare to claims per your instructions as well as the various Value Claims you reviewed and one Waterproof graphic to go with the existing claim. The language in green is the language that we discussed in face to face meeting with with Richard and again with Bo in regards to the Bulk Vet packaging. In the Header the original document was Version 15.1, this newer document is Version 15.1a so you can tell the two apart.

Please let me know if you have any questions.

Please, note the change in my email address.

Kelly Hoskins | Manager of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: kelly.hoskins@perrigo.com | sergeants.com



From: Chao, Julie [mailto:Chao.Julie@epa.gov]
Sent: Tuesday, July 07, 2015 9:16 AM
To: Kelly Hoskins
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Hi Kelly,

Thanks for getting in touch and for following-up on these labels. I'm sorry for the delay....I have it in my notes that I owe you label comments.

I am free at 4:00pm ET. Do you want to call me at my desk, (703) 308-8735?

Thanks,
Julie

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Tuesday, July 07, 2015 10:01 AM
To: Chao, Julie
Subject: FW: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Julie,
I am following up on these labels to see where we stand, are you available for a phone call today.

Also I have my QA asking a clarification question on 2517-118 CSF that you reviewed and was accepted April 21st, I think it would be easier to explain over the phone.

I have EST 1030-1200 and 400pm and later open if that will work for you.

Kelly Hoskins | Manager of Regulatory Affairs
Perrigo Animal Health
T: (402) 938-7079
F: (402) -938-7179
E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

Quality Affordable Healthcare Products® for Pets!



From: Kelly Hoskins
Sent: Thursday, May 21, 2015 7:54 AM
To: 'Chao, Julie'
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

roger

Kelly Hoskins | Manager of Regulatory Affairs
Perrigo Animal Health
T: (402) 938-7079
F: (402) -938-7179
E: kelly.hoskins@perrigo.com | perrigoanimalhealth.com

From: Chao, Julie [<mailto:Chao.Julie@epa.gov>]
Sent: Thursday, May 21, 2015 7:53 AM

To: Kelly Hoskins
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Thanks for bringing this up, Kelly. Let me discuss with Bo and Autumn before I have you send something in.

Thanks,
Julie

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Thursday, May 21, 2015 8:47 AM
To: Chao, Julie
Cc: Prince Bamaze
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Julie,
It hit me last night that I did not talk to you about the vet bulk packaging that we discussed with Bo last month while we were there talking about the CRP changes. We presented the language that we have used on other spot on products 2517-155/156 as well as suggestive language. We currently have sister products in review with Autumn. I would like to add these if I may and I can send them to you in the next 60 minutes or so as I get them incorporated into this label if you are acceptable to that.

Kelly Hoskins | Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: khoskins@sergeants.com | sergeants.com



From: Chao, Julie [<mailto:Chao.Julie@epa.gov>]
Sent: Wednesday, May 20, 2015 3:02 PM
To: Kelly Hoskins
Cc: Prince Bamaze
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Thanks, Kelly. I will discuss with the PM and get back to you this week.
Julie

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Wednesday, May 20, 2015 3:52 PM
To: Chao, Julie

Cc: Prince Bamaze

Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Julie,

I forgot to add in the Merial information as we discussed. Below is the link from the web site that is on the most recently accepted label on PPLS that shows the website www.frontline.com, thus an extension of the label.

Once you go to the web site at the bottom are the claims listed below and after clicking that link it takes you to more claims and information.

<http://www.frontline.com/Pages/default.aspx>

Vet's #1 Choice.¹

Learn why FRONTLINE Plus is the vet's #1 choice for their pets and yours.²

Here is the survey we discussed as well as the break out of the #1 Vet claims on a single page with anything new in blue. I left the all there but I think we can focus on the top half of the claims, now that they are broken out.

Please let me know if there are any questions.

Kelly Hoskins | Regulatory Affairs

Sergeant's Pet Care Products, Inc.

A Perrigo Company

10077 South 134th Street

Omaha, NE 68138-3710

T: 402.938.7079

F: 402.938.7179

E: khoskins@sergeants.com | sergeants.com



From: Chao, Julie [<mailto:Chao.Julie@epa.gov>]

Sent: Tuesday, May 19, 2015 8:59 AM

To: Kelly Hoskins

Cc: Prince Bamaze

Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Hi Kelly,

Talk to you at 3pm. You can reach me at my desk, (703) 308-8735.

Thanks,

Julie

+++++

Julie Chao, MA, MSPH

Invertebrate & Vertebrate Branch 1

Registration Division
Office of Pesticide Programs
703.308-8735 (phone)

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Tuesday, May 19, 2015 9:57 AM
To: Chao, Julie
Cc: Prince Bamaze
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Julie,
3pm EST will work just fine.

Do you want to call me or me call you, if so at what number?

Kelly Hoskins | Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: khoskins@sergeants.com | sergeants.com



From: Chao, Julie [<mailto:Chao.Julie@epa.gov>]
Sent: Tuesday, May 19, 2015 6:57 AM
To: Kelly Hoskins
Cc: Prince Bamaze
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Hi Kelly,

Thanks for getting in touch about the labels. A phone call sounds like a good idea. Does 11:30am, 1:00pm, or 3:00pm ET work for you?

Thanks,
Julie

From: Kelly Hoskins [<mailto:Kelly.Hoskins@perrigo.com>]
Sent: Monday, May 18, 2015 3:54 PM

To: Chao, Julie
Cc: Prince Bamaze
Subject: RE: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Julie,
I am back in the office and going through emails and labels and I have some comments and questions for you on these items below.

I did only the first one as the four are basically the same issues and once done I will make the same to the others in a very short amount of time.

Once you review I would like to have a phone call as I think it can go faster in discussion.

Kelly Hoskins | Regulatory Affairs
Sergeant's Pet Care Products, Inc.
A Perrigo Company
10077 South 134th Street
Omaha, NE 68138-3710
T: 402.938.7079
F: 402.938.7179
E: khoskins@sergeants.com | sergeants.com



From: Chao, Julie [<mailto:Chao.Julie@epa.gov>]
Sent: Tuesday, May 05, 2015 12:35 PM
To: Kelly Hoskins
Subject: Label Comments: 2517-134, 2517-135, 2517-136, 2517-137

Hi Kelly,

I am reviewing your label amendment applications for EPA Reg. Nos. 2517-134, -135, -136, and -137. Please see my comments below. I believe these requested changes are consistent with changes approved recently for similar Sergeant's applications (e.g., Reg. No. 2517-166). Let me know if you have any questions. Otherwise, please email a revised label.

2517-134 Label Comments

- The proposed weight classifications are acceptable. Roger
- Page 3: All comparative claims must reference BOTH active ingredients, and a substantially similar product containing BOTH of the same active ingredients. "Frontline brand products" is too vague and must be deleted. Removed Also, the word "same" in the statement "contains the same active..." must NOT have brackets. Please revise accordingly. These have been modified beyond just adding in the "same" as it made some of them

grammatically confusing. Ended up removing those that had "an" in the sentence so we ended with fewer statements overall.

- Page 4: ALL proposed claims are unacceptable due to implied safety/efficacy (e.g., #1, vet recommended) and lack of enforceability (e.g., vet dispensed). Please delete. I did not remove yet as these are the ones I would like to discuss further to get a better understanding for the reason of both groups.
- Pages 6 & 7: Under the directions for use, the phrase "[directly to skin]" is not optional. Please delete the brackets. The product MUST be applied to the skin to be efficacious.
This is a secondary redundant reminder since all products have the required How to Apply section above that already state application to skin which is the primary directions and the weight break information is the second portion of the directions.

2517-135 Label Comments

- Page 3: All comparative claims must reference BOTH active ingredients, and a substantially similar product containing BOTH of the same active ingredients. "Frontline brand products" is too vague and must be deleted. Also, the word "same" in the statement "contains the same active..." must NOT have brackets. It is NOT appropriate to compare a cat product to dog products. Please revise accordingly.
- Page 4: ALL proposed claims are unacceptable due to implied safety/efficacy (e.g., #1, vet recommended) and lack of enforceability (e.g., vet dispensed). Please delete.
- Page 6: Under the directions for use, the phrase "[directly to skin]" is not optional. Please delete the brackets. The product MUST be applied to the skin to be efficacious.
- Please correct pagination. The last page reads, "Page 10 of 9."

2517-136 Label Comments

- The proposed weight classifications are acceptable.
- Page 4: All comparative claims must reference a substantially similar product. "Frontline brand products" is too vague and must be deleted. Also, the word "same" in the statement "contains the same active..." must NOT have brackets. Please revise accordingly.
- Pages 4 and 5: ALL proposed claims are unacceptable due to implied safety/efficacy (e.g., #1, vet recommended) and lack of enforceability (e.g., vet dispensed). Please delete.
- Page 7: Under the directions for use, the phrase "[directly to skin]" is not optional. Please delete the brackets. The product MUST be applied to the skin to be efficacious.

2517-137 Label Comments

- Page 3: For the comparative claims, the word "same" in the statement "contains the same active..." must NOT have brackets. It is NOT appropriate to compare a cat product to dog products. Please revise accordingly.
- Page 4: ALL proposed claims are unacceptable due to implied safety/efficacy (e.g., #1, vet recommended) and lack of enforceability (e.g., vet dispensed). Please delete.
- Page 6: Under the directions for use, the phrase "[directly to skin]" is not optional. Please delete the brackets. The product MUST be applied to the skin to be efficacious.
- Please correct pagination. The last page reads, "Page 9 of 8."

Thanks,

Julie

+++++

Julie Chao, MA, MSPH

Invertebrate & Vertebrate Branch 1

Registration Division

Office of Pesticide Programs

703.308-8735 (phone)

NOTICE: This e-mail message and any attachments are confidential and intended solely for use of the intended recipient. If you are not the intended recipient, you should not review, retransmit, convert to hard copy, copy,

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature:

Date: _____

PM #:

3

EPA Reg. Number: 2817-134		EPA Receipt Date: 2/19/15		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?			
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)	✓		
	a) Electronic Label submitted?			
Comments:				

S: 964524 Milestone: Mail:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 3

Product #: 2517-134 Product Name: SERGEANT'S FIPRONIL + METHOPRENE SQUI

Override#:

Me Too Section3: 65331-5 Me Too Product Name: FRONTLINE PLUS FOR DOGS

Application Date: 18-Feb-2015

OPP Rec'd Date: 19-Feb-2015

Front End Date: 19-Feb-2015

Risk Manager Send Date: 20-Feb-2015

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NON PRIA LABEL AMENDMENT

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Paper Label

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 20, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. KELLY R. HOSKINS
SERGEANT'S PET CARE PRODUCTS, INC.
PO Box 540399
OMAHA, NE 68154-0399

PRODUCT NAME: SERGEANT'S FIPRONIL + METHOPRENE SQUEEZE-ON FOR DOGS
COMPANY NAME: SERGEANT'S PET CARE PRODUCTS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2517-134
EPA RECEIPT DATE: 02/19/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 306-0415.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]", is written over the typed name.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

8

Fee for Service

{964524+~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 3

Receipt No.

S-

964524

EPA File Symbol/Reg. No.

2517-134

Pin-Punch Date:

2/19/2015

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ ____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: 

Date: 2-20-15

Remarks:

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-134		2. EPA Product Manager Kable Davis	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Fipronil + Methoprene Squeeze-On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-1710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section II			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Non-PRIA label amendment. Please see cover letter for details.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.023 fl oz, 0.045 fl oz, 0.091 fl oz, 0.136 fl oz	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. 1,2,3,4,5,6, 12,24 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.023 fl oz (0.67 ml), 0.045 fl oz (1.34 ml), 0.091 fl oz (2.68 ml), 0.136 fl oz (4.02 ml)	
5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application..)			
Name Kelly R. Hoskins		Title Director of Regulatory Affairs	
		Telephone No. (Include Area Code) 402-938-7079	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>		3. Title Director of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins		5. Date: 2/17/2015	



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138-3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

February 18, 2015

Kable Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (AMEND)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Application for Pesticide Amendment (Revised Label) for
Sergeant's Fipronil + Methoprene Squeeze-On for Dogs,
EPA Registration Number 2517-134

Dear Mr. Davis:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting an application for pesticide amendment to revise the master label for the end-use product, Sergeant's Fipronil + Methoprene Squeeze-On for Dogs (EPA Registration Number 2517-134). The following items are enclosed in support of this non-PRIA3 label amendment action:

- Application for Pesticide Amendment (EPA Form 8570-1);
- Product master label v15.1 (5 copies, one copy with all changes highlighted); and
- EPA stamped notification letter/label dated January 22, 2015 (for Agency's reference).

All changes that differ from the current EPA label dated January 22, 2015 are highlighted on one copy of the revised label, and are as follows:

- This registration has been reviewed and accepted as meeting the Agency's pet spot-on mitigation measures (EPA stamped letter/label dated September 11, 2013). The companion animal safety data were reviewed and accepted to support the 4 lb minimum dog weight on the label. Although the data support a 4 lb minimum weight, there are instances where Sergeant's may use a 5 lb minimum dog weight for market label purposes, and has added, as an option, a 5 lb minimum dog weight.
- Further, Sergeant's has added multiple, new optional active ingredient reference statements.
- Finally, Sergeant's has added text to the How to Apply section in order to clarify the directions for use.

Note that these revisions do not necessitate any data review.

If you have any questions regarding this submission, please contact me at 402-938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Director of Regulatory Affairs

Enclosures

Sergeant's Master Label

11 Feb 2015 Amendment
Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs:]

[Sergeant's® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sergeant's® Ectoadvance Plus (Spot On) for Dogs]

[Sergeant's® AdvanSpot Plus (Spot On) for Dogs]

[Sergeant's® PRONYL OTC™ PLUS for Dogs]

[SentryProline Plus (Spot On) for Dogs]

[SENTRY® FIPROGUARD™ PLUS for Dogs]

[SENTRY® AdvanSpot Plus (Spot On) for Dogs]

[Sentry® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sentry® Ectoadvance Plus (Spot On) for Dogs]

[PetArmor® Plus for dogs]

[Sergeant's® PetArmor® Plus for dogs]

[1.5cm x 1.5cm on final or as indicated]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR}

For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age {OR}

For use ONLY on dogs [[&][and] puppies 5[-] [to] 22 lbs and over 8 weeks of age {OR} ✓

ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] {OR}

ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-][to] 22 lbs {OR}

ONLY For Dogs & Puppies 8 weeks or older [&][and] 5[-][to] 22 lbs ✓

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea

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pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]

[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [Brand Name][This product] monthly to break the flea life cycle.]

[Use [Brand Name][This product] monthly to control ticks and chewing lice]

[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]

[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]

[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]

[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]

[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]

[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]

[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]

[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]

[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]

[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]

[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]

[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]

[With (S)-methoprene to Break Flea Life Cycle]

[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]

[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]

[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]

[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]

[Prevents Flea Eggs From Developing Into Biting Adults]

[Prevents all stages of the flea life cycle from developing]

[Controls reinfestation of fleas for up to 3 months]

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[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

[All Others]

[For Dogs and Puppies 8 weeks of age or older]
[Can be used on puppies 8 weeks of age and older]
[Specially Formulated for Dogs and Puppies 8 weeks of age or older]
[For Dogs [4-22 lbs.], [5-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.] ✓
[Fast Acting] [Long Lasting]
[Convenient spot treatment]
[Easy to Use [Application]]
[Best if used year round!]
[For year-round protection, apply [Brand Name] monthly]
[(ICON Showing [4 week] [1 month] [30 day] Protection)]
[Apply monthly]
[Prevents reinfestation of listed pests for [4 weeks] [1 month]]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Controls mites that may cause sarcoptic mange]
[Waterproof]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]
[[Free] Calendar Stickers Inside!]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]
[Fipronil (9.8%) + (S)-methoprene (8.8%)]
[Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*]
[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in: [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

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[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].]

[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®] [Company name].]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[1][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information] ✓

[S][Small][4-22 lbs.][5-22 lbs.][M][Medium][23-44 lbs.][L][Large][45-88 lbs.][XL][Extra Large][89-132 lbs.]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

[[#1] vet[erinarian] recommended flea & tick active ingredient combination]

[Contains [fipronil and S-methoprene] [the #1] vet[erinarian] recommended flea & tick active ingredient combination]

[Contains [fipronil and S-methoprene] [a] vet[erinarian] recommended flea & tick active ingredient combination]

[#1 vet dispensed flea & tick active ingredient combination]

[#1 flea & tick active ingredient combination dispensed in the vet channel]

[Contains the #1 vet dispensed active ingredient combination]

[Contains the #1 active ingredient combination dispensed in the vet channel]

[[#1] vet[erinarian] recommended active ingredient combination*]

[[#1] vet[erinarian] dispensed active ingredient combination*]

[Contains fipronil and S-methoprene, an active ingredient combination recommended by vet[erinarian]s]*

[*among flea and tick products]

[[#1] vet[erinarian] dispensed flea & tick active ingredient combination]

[[#1] vet[erinarian] recommended flea & tick active ingredient combination]

[Contains [fipronil and S-methoprene] [the #1] [a] vet[erinarian] dispensed flea & tick active ingredient combination]

[Contains [fipronil and S-methoprene] [the #1] [a] vet[erinarian] recommended flea & tick active ingredient combination]

[[Vet[erinarian] Quality [flea & tick] [active ingredient combination]]]

ACTIVE INGREDIENTS:

Fipronil 9.80%

(S)-methoprene 8.80%

OTHER INGREDIENT: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

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Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) [applicators][tubes][vials][pipettes]]
[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
[0.023 fl oz (0.67 mL)] [0.045 fl oz (1.34 mL)] [0.091 fl oz (2.68 mL)] [0.136 fl oz (4.02 mL)]
[applicators][tubes][vials][pipettes]
{END - FRONT PANEL}

BACK /SIDE PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Brand Name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

FIRST AID	
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs.

Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4

✓ (or 5)][23][45][89] lbs. Use entire contents of [tube] [vial] [applicator] [pipette] on each dog. [Do not split one [tube] [vial] [applicator] [pipette] between dogs.] Do not use multiple [tube] [vial] [applicator]

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[pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, ~~contact~~ your veterinarian.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert [tube] [vial] [applicator] [pipette] over dog and use open end to part dog's hair. Squeeze tube [vial] [applicator] [pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs. {OR}

Only For Dogs Weighing 5 [-] [to] 22 lbs. Do not apply to dogs weighing less than 5 lbs. ✓

[including small dogs and puppies, 8 weeks or older]:

Apply one [tube] [vial] [applicator] [pipette] (0.67 mL)(0.023 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on] [to] the dog's back between the shoulder blades] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.] ✓

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs. Do not apply to dogs weighing less than 23 lbs. ✓

Apply one [tube] [vial] [applicator] [pipette] (1.34 mL)(0.045 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on] [to] the dog's back between the shoulder blades] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs. Do not apply to dogs weighing less than 45 lbs. ✓

Apply one [tube] [vial] [applicator] [pipette] (2.68 mL)(0.091 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on] [to] the dog's back between the shoulder blades] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not apply to dogs weighing less than 89 lbs. Do not use ✓

Sergeant's Master Label

11 Feb 2015 Amendment
Information in [] is optional.

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two tubes on dogs greater than 132 lbs Apply one [tube] [vial] [applicator] [pipette] (4.02 mL)(0.136 fl oz) [directly to skin] [from the back of the neck to a point midway between the neck and tail] [as a spot [on] [to] the dog's back between the shoulder blades] [as a [stripe][line] starting [at the middle of the back][at a midway point between the neck and tail] and ending [at a spot] between the shoulder blades]. [This allows for a more direct application to the skin.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/[25°C]]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box]
Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA] [U.S. Patent No. 5,567,429]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-134
EPA Est. No. [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

Sergeant's Master Label

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Information in [] is optional.

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[[Clip. Part. Squeeze.]]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea and tick protection where it needs to be.]

[Application Instructions] [Directions for Use]

How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert [tube] [vial] [applicator] [pipette] over dog and use open end to part dog's hair.
2. Squeeze [tube] [vial] [applicator] [pipette] firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Brand Name][This Product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application date][Date of Application]

[calendar stickers with [Brand Name] [This Product]

[Place stickers on your calendar as a reminder to reapply [Brand Name] [This Product] in 30 days.]

[Place sticker on your calendar or [refrigerator] to remind yourself to apply [Brand name][this product] to your dog]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[33% more free]

[Bonus Size]

[Buy 3 get 1 free]



























Sergeant's Master Label

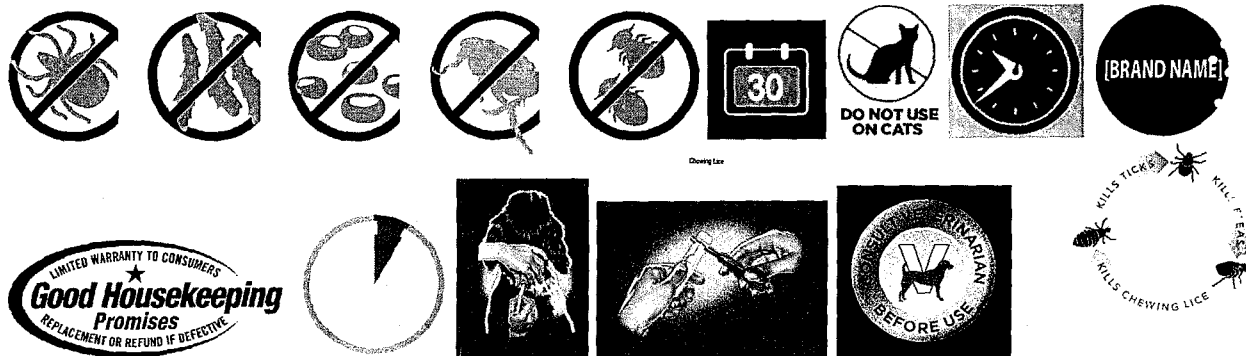
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[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	



MADE IN THE
USA

MADE IN THE
USA
WITH GLOBAL MATERIALS



Sergeant's Master Label

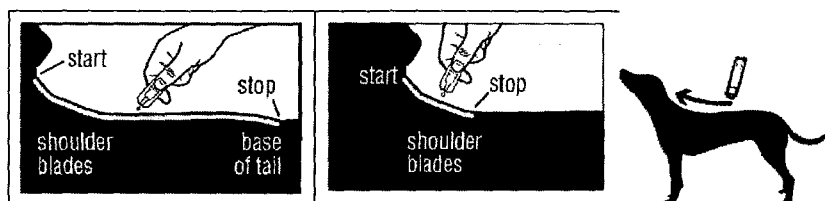
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Information in [] is optional.

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[Flea life cycle diagram] [Flea Life Cycle]



{END - PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

{Front Label}

{Back Label}

{Brand Name}

For Dogs [X-Y] lbs \geq 8 wks

fipronil 9.8%, s-methoprene 8.8%

0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)

0.136 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 2517-134

{label code}

{EPA REG No may be on either the front or back label}

{END - TUBE/VIAL LABEL}



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 10, 2015

Kelly Hoskins
Sergeant's Pet Care Products, Inc.
10077 S. 134th St.
Omaha, NE 68138

Subject: Condition of Registration – Storage Stability and Corrosion Characteristics Data
Product Name: SERGEANT'S FIPRONIL + METHOPRENE SQUEEZE-ON
FOR DOGS
EPA Registration Number: 2517-134
Application Date: November 21, 2012
Decision Number: 458416

Dear Mr. Hoskins:

The Agency has reviewed the studies submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The studies have been classified as acceptable. The condition of registration is considered fulfilled.

If you have any questions, please contact Maggie Rudick by phone at 703-347-0257, or via email at rudick.maggie@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Maggie Rudick" with "for" written below it.

Kable Bo Davis, Product Manager 3
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure DP426064



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: April 20, 2015

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW
ACCELERATED STUDY ☐ ; ONE YEAR STUDY ☒;
OVER 1 YEAR STUDY ☐
MP ☐ EP ☒ EUP ☐
DP BARCODE No.: 426064 REG. No.: 2517-134 FILE SYMBOL No.:
DECISION No.: 458416 MRID No(s): 489995-01
PRODUCT NAME: Sergeant's Fipronil + Methoprene Squeeze-on for Dogs
COMPANY: SERGEANT'S PET CARE PRODUCTS, INC

FROM: Linda Mascall / Shyam Mathur *Linda Mascall*
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/RD (7505P) *SBM 4/21/15*

TO: Linda DeLuise / Kable Davis, RM 03
Invertebrate and Vertebrate Branch 2 / RD (7505P)

I. CONCLUSIONS:

STORAGE STABILITY (830.6317):

☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):

☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

The product is a solution of Fipronil + Methoprene in an organic solvent matrix and is to be sold in plastic squeeze-on ampoules. After 12 months at room temperature the filled commercial ampoules showed no paneling, crazing or discoloration of any kind. To date the product is non-reactive to the commercial container.

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient(s): Fipronil; (S)-methoprene

Label claim(s) Nominal concentration(s) (%): 9.80; 8.80

Initial concentration(s) of the AI(s) (%) used in the study: 9.63; 8.96

Lower certified limits (%) based on AI % in the study: 9.3185; 8.352

C. EXPERIMENTAL PARAMETERS

Temperature: ☐ Freezer; Room ☒; Warehouse ☐; 54°C ☐; Other ☐

Humidity: Indicate % (if provided)

Duration of study: ☒ 1 year; ☐ over 1 year

Type of container: ☐ Glass; ☐ Metal; ☐ HDPE; ☒ Fluorinated HDPE; ☐ Other

Analysis at intervals: ☒ 0 (initial);

☒ 3 months; ☒ 6 months

☒ 9 months; ☒ 12 months

☐ Over 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
Gas chromatography (GC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
Capillary Gas chromatography (CGC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
High Pressure Liquid chromatography (HPLC)	<input checked="" type="checkbox"/> UV/VIS (nm) - 274 (nm) <input type="checkbox"/> RI (Refractive Index) <input type="checkbox"/> Other
GC-MS / LC-MS	Specify
Other	Specify

E. RESULTS

Active Ingredient	Storage time (months)				
	Initial	3 month	6 month	9 month	12 month
Fipronil rep 1	9.66	9.68	9.44	9.69	9.64
Fipronil rep 2	9.67	9.67	9.55	9.64	9.64
Fipronil rep 3	9.55	9.67	9.59	9.54	9.51
Fipronil mean	9.63	9.67	9.53	9.62	9.60
Methoprene rep 1	8.98	8.93	8.89	8.87	8.80
Methoprene rep 2	8.88	8.96	8.97	8.74	8.92
Methoprene rep 3	9.01	8.94	8.99	8.73	8.86
Methoprene mean	8.96	8.94	8.95	8.78	8.86

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs is chemically stable after 12-months at room temperature.

PROCESSING REQUEST

Reg #: 2517-134

Decision #:498493

Description: Label amendment.

Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated: 1/22/2015

☐ Other:

Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐ Notification Dated:

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jen Gaines

Division: RD

Phone: 305-5967

Date: 1/22/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 22, 2015

Ms. Kelly Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th St
Omaha, NE 68138

Subject: Label Notification per PRN 98-10 – Adding optional text and graphics.
Product Name: Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Registration Number: 2517-134
Application Date: 12/12/2014
Decision Number: 498493

Dear Ms. Hoskins:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jennifer Gaines" followed by a small mark.

Kable Bo Davis, Product Manager 03
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Sergeant's Master Label

12 DEC 2014 Notification
Information in [] is optional.

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Supersedes Pending Amend 3/06/2014

FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs:]

[Sergeant's® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sergeant's® Ectoadvance Plus (Spot On) for Dogs]

[Sergeant's® AdvanSpot Plus (Spot On) for Dogs]

[Sergeant's® PRONYL OTC™ PLUS for Dogs]

[SentryProline Plus (Spot On) for Dogs]

[SENTRY® FIPROGUARD™ PLUS for Dogs]

[SENTRY® AdvanSpot Plus (Spot On) for Dogs]

[Sentry® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sentry® Ectoadvance Plus (Spot On) for Dogs]

[PetArmor® Plus for dogs]

[Sergeant's® PetArmor® Plus for dogs]

NOTIFICATION

2517-134

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

01/22/2015

[1.5cm x 1.5cm on final or as indicated]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR}

For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age {OR}

ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] {OR}

ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-][to] 22 lbs {OR}

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

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[Breaks the Flea Life Cycle [for up to three months]]
[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]
[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]
[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]
[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]
[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Use [Brand Name][This product] monthly to break the flea life cycle.]
[Use [Brand Name][This product] monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks],][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]
[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If dog is a high risk for flea reinfestation a once month application may be needed]
[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Prevents all stages of the flea life cycle from developing]
[Controls reinfestation of fleas for up to 3 months]
[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

Sergeant's Master Label

12 DEC 2014 Notification
Information in [] is optional.

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Supersedes Pending Amend 3/06/2014

[All Others]

[For Dogs and Puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [4-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]

[Fast Acting] [Long Lasting]

[Convenient spot treatment]

[Easy to Use [Application]]

[Best if used year round!]

[For year-round protection, apply [Brand Name] monthly]

[(ICON Showing [4 week] [1 month] [30 day] Protection)]

[Apply monthly]

[Prevents reinfestation of listed pests for [4 weeks] [1 month]]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]

[Controls mites that may cause sarcoptic mange]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]

[[Free] Calendar Stickers Inside!]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]

[Fipronil (9.8%) + (S)-methoprene (8.8%)]

[Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)]

[FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*]

[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].]

Sergeant's Master Label

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[[Brand Name]][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]
[Company name].]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[1]][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

[S][Small][4-22 lbs.][M][Medium][23-44 lbs.][L][Large][45-88 lbs.][XL][Extra Large][89-132 lbs.]

[Direct to skin [tube][vial][applicator][pipette]]

[Easy to Use] [tube][vial][applicator][pipette]]

[Clean cut [open] [tube][vial][applicator][pipette]]

[No-mess [open] [tube][vial][applicator][pipette]]

[Clip-tip design [tube][vial][applicator][pipette][!]]

[Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-methoprene..... 8.80%

OTHER INGREDIENT: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) [applicators][tubes][vials][pipettes]]
[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
[0.023 fl oz (0.67 mL)] [0.045 fl oz (1.34 mL)] [0.091 fl oz (2.68 mL)] [0.136 fl oz (4.02 mL)]
[applicators][tubes][vials][pipettes]
{END - FRONT PANEL}

BACK /SIDE PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Brand Name]][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name]][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs.

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Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

FIRST AID	
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs. Use entire contents of [tube] [vial] [applicator] [pipette] on each dog. [Do not split one [tube] [vial] [applicator] [pipette] between dogs.] Do not use multiple [tube] [vial] [applicator] [pipette]s on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert [tube] [vial] [applicator] [pipette] over dog and use open end to part dog's hair. Squeeze tube [vial] [applicator] [pipette] firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

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{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs.

[including small dogs and puppies, 8 weeks or older]:

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs.

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs. Apply one tube (2.68 mL)(0.091 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not use two tubes on dogs greater than 132 lbs

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

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In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box]
Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA] [U.S. Patent No. 5,567,429]

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-134
EPA Est. No. [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[[Clip. Part. Squeeze.]

Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting proven flea and tick protection where it needs to be.]

[Application Instructions] [Directions for Use]

How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert [tube] [vial] [applicator] [pipette] over dog and use open end to part dog's hair.
2. Squeeze [tube] [vial] [applicator] [pipette] firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][This Product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application date][Date of Application]

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[calendar stickers with **[Brand Name]** [This Product]

[Place stickers on your calendar as a reminder to reapply **[Brand Name]** [This Product] in 30 days.]

[Place sticker on your calendar or [refrigerator] to remind yourself to apply **[Brand name]**[this product] to your dog]

[Monthly Application Reminder Magnet (image of reminder magnet)]























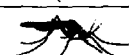



[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply **[Brand Name]**[This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[33% more free]

[Bonus Size]

[Buy 3 get 1 free]

[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

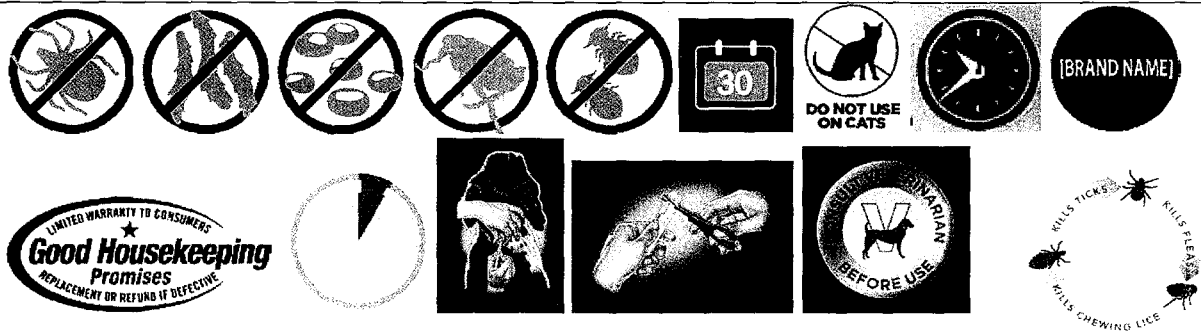
Sergeant's Master Label

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Information in [] is optional.

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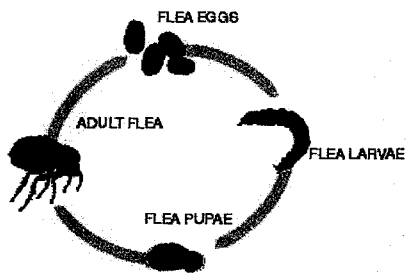
EPA No. 2517-134
EPA SAL 9/11/2013

Supersedes Pending Amend 3/06/2014

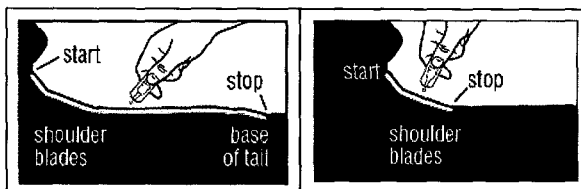


MADE IN THE
USA

MADE IN THE
USA
WITH GLOBAL MATERIALS



[Flea life cycle diagram] [Flea Life Cycle]



{END - PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON
FIPRONIL+METHOPRENE

{Front Label}

{Back Label}

{Brand Name}

For Dogs [X-Y] lbs ≥ 8 wks

fipronil 9.8%, s-methoprene 8.8%

0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)

0.136 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 2517-134

{label code}

{EPA REG No may be on either the front or back label}

{END - TUBE/VIAL LABEL}



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138-3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

December 17, 2014

Kable Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Application for Pesticide Notification (Revised Label) for
Sergeant's Fipronil + Methoprene Squeeze-On for Dogs,
EPA Registration Number 2517-134

Dear Mr. Davis:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting an application for pesticide notification to revise the master label for the end-use product, Sergeant's Fipronil + Methoprene Squeeze-On for Dogs (EPA Registration Number 2517-134) as permitted by Pesticide Registration Notice 98-10. The following items are enclosed in support of this label notification action:

- Application for Pesticide Notification (EPA Form 8570-1);
- Product master label v14.3 (2 copies, one copy with all changes highlighted); and
- EPA stamped accepted letter/label dated September 11, 2013 (for Agency's reference).

Sergeant's is revising the master label to add new optional text and graphics, such as: [vial] [tube] [applicator] [pipette]; [S][Small][M][Medium] etc; [Clip. Part. Squeeze.]; and [Satisfaction Guaranteed][If you are not satisfied, we will make it right with a replacement or refund] and other minor revisions. All changes from the currently approved EPA label dated September 11, 2013 are highlighted on one copy of the revised label. Further, the current label (enclosed) has been reviewed and accepted as meeting the Agency's pet spot-on mitigation measures.

Please note that Sergeant's submitted an Amendment to revise the label on March 6, 2014 and we understand this Notification will supersede the pending Amendment.

If you have any questions regarding this submission, please contact me at 402-938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins
Director of Regulatory Affairs

Enclosures

EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
---	---	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 2517-134	2. EPA Product Manager Kable Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Fipronil + Methoprene Squeeze-On for Dogs	5. PM # 3	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-1710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.
---	---

Explanation: Use additional page(s) if necessary. (For section I and Section II.) This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sec 12 and 14 of FIFRA. Please see cover letter for details.

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.023 fl oz, 0.045 fl oz, 0.091 fl oz, 0.136 fl oz	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1,2,3,4,5,6, 12,24 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 0.023 fl oz (0.67 ml), 0.045 fl oz (1.34 ml), 0.091 fl oz (2.68 ml), 0.136 fl oz (4.02 ml)		5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelly R. Hoskins	Title Director of Regulatory Affairs	Telephone No. (Include Area Code) 402-938-7079
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>	3. Title Director of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins	5. Date: 12/12/2014	

Receipt for Section 3



S: 961850 Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 3

Product #: 2517-134 Product Name: SERGEANT'S FIPRONIL + METHOPRENE SQUI

Override#:

Me Too Section3: 65331-5 Me Too Product Name: FRONTLINE PLUS FOR DOGS

Application Date: 12-Dec-2014



OPP Rec'd Date: 17-Dec-2014



Front End Date: 17-Dec-2014



Risk Manager Send Date: 17-Dec-2014



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label Notification to add new optional text and graphics



Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content	Des
Paper Label	<input type="text"/>
<input type="text"/>	

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT - 9 2014

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
Manager of Technical Affairs
2625 South 158th Plaza
Omaha, NE 68130-1770

Subject: Storage Stability and Corrosion Data
Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Registration Number: 2517-134
Date of Submission: November 17, 2011
Decision: 458416

Dear Ms. Hoskins:

The Technical Review Branch has completed their review of the Storage Stability and Corrosion Data and finds it to be acceptable. A copy of the findings for this product has been placed in the subject file for this product.

If you have any questions please, contact Melody Banks on 703 305 5413 or via e-mail @melody.banks@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Copy of Product Review



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: September 29, 2014

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW
ACCELERATED STUDY ☒; ONE YEAR STUDY ☐
OVER 1 YEAR STUDY ☐
MP ☐ EP ☒ EUP ☐
DP BARCODE No.: 397340 REG. No.: 2517-134 FILE SYMBOL No.:
DECISION No.: 458416 MRID No(s): 486599-01
PRODUCT NAME: Sergeant's Fipronil + Methoprene Squeeze-on for Dogs
COMPANY: SERGEANT'S PET CARE PRODUCTS, INC.

FROM: Linda Mascall / Shyam Mathur
Product Chemistry Team
Technical Review Branch/RD (7505P)

Linda Mascall
SRB 9/30/14

TO: Melody Banks / Richard Gebken, RM 10
Insecticide Branch / RD (7505P)

I. CONCLUSIONS:

STORAGE STABILITY (830.6317):
☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):
☒ ACCEPTABLE
☐ UNACCEPTABLE*
☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

The product is a solution of Fipronil + Methoprene in an organic solvent matrix and is to be sold in plastic squeeze-on ampoules. After 6 months at room temperature the filled commercial ampoules showed no paneling, crazing or discoloration of any kind. To date the product is non-reactive to the commercial container.

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient(s): Fipronil; (S)-methoprene

Label claim(s) Nominal concentration(s) (%): 9.80; 8.80

Initial concentration(s) of the AI(s) (%) used in the study: 9.63; 8.96

Lower certified limits (%) based on AI % in the study: 9.3185; 8.352

C. EXPERIMENTAL PARAMETERS

Temperature: ☐ Freezer; Room ☐; Warehouse ☒; 54°C ☐; Other ☐

Humidity: Indicate % (if provided)

Duration of study: ☐ 1 year; ☐ over 1 year

Type of container: ☐ Glass; ☐ Metal; ☐ HDPE; ☒ Fluorinated HDPE; ☐ Other

Analysis at intervals: ☒ 0 (initial);

☒ 3 months; ☒ 6 months

☐ 9 months; ☐ 12 months

☐ Over 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
Gas chromatography (GC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
Capillary Gas chromatography (CGC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
High Pressure Liquid chromatography (HPLC)	<input checked="" type="checkbox"/> UV/VIS (nm) - 274 nm <input type="checkbox"/> RI (Refractive Index) <input type="checkbox"/> Other
GC-MS / LC-MS	Specify
Other	Specify

E. RESULTS

Active Ingredient	Storage time (months)		
	Initial	3 month	6 month
Fipronil rep 1	9.66	9.68	9.44
Fipronil rep 2	9.67	9.67	9.55
Fipronil rep 3	9.55	9.67	9.59
Fipronil mean	9.63	9.67	9.53
Methoprene rep 1	8.98	8.93	8.89
Methoprene rep 2	8.88	8.96	8.97
Methoprene rep 3	9.01	8.94	8.99
Methoprene mean	8.96	8.94	8.95

DATA PACKAGE BEAN SHEET

Date: 03-Jan-2012

Page 1 of 2

Decision #: 458416

DP #: (397340)

NON PRIA

Parent DP #:

Submission #: 907147

E-Sub #:

*** Registration Information ***

Registration: 2517-134 - SERGEANT'S FIPRONIL + METHOPRENE SQUEEZE-ON FOR

Company: 2517 - SERGEANT'S PET CARE PRODUCTS, INC.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Melody Banks MBANKS

Sent Date: 17-Nov-2011

Calculated Due Date: 06-Mar-2012

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (570) CONDITIONAL REGISTRATION FOLLOW-UP; DATA REQUIRED; REQUIRES RD REVII

Ingredients: 105402, S-Methoprene(8.8%)

129121, Fipronil(9.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 03-Jan-2012

Due Back: _____

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: _____

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB - Chem

Last Possible Science Due Date: 27-Dec-2011

Team Name: _____

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Interim Storage Stability and Corrosion Characteristics study as a condition of registration.

570
#29955

3-22-2017

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48659901		Bradbury, R. (2011) Product Chemistry: Measurement of Storage Stability & Corrosion Characteristics of Sergeant's Fipronil + Methoprene Squeeze-On for Dogs. Project Number: ECS294/1B. Unpublished study prepared by EcoSafe Natural Products, Inc. 26p.	830.6317/Storage stability	Pass (19-Dec-2011)
48659901		Bradbury, R. (2011) Product Chemistry: Measurement of Storage Stability & Corrosion Characteristics of Sergeant's Fipronil + Methoprene Squeeze-On for Dogs. Project Number: ECS294/1B. Unpublished study prepared by EcoSafe Natural Products, Inc. 26p.	830.6320/Corrosion characteristics	Pass (19-Dec-2011)

November 17, 2011

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Interim Storage Stability and Corrosion Characteristics studies for two registrations (Sergeant's Fipronil + Methoprene Squeeze-On for Dogs, EPA Reg. No. 2517 – 134 and Sergeant's Fipronil Squeeze-On for Dogs, EPA Reg. No. 2517 – 136)

Dear Mr. Gebken:

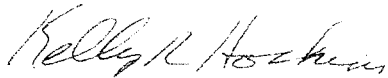
Sergeant's Pet Care Products, Inc. (Sergeants, 2625 South 158th Plaza, Omaha, NE 68130-1770, EPA Company Number 2517) is submitting Interim Storage Stability and Corrosion Characteristics (OPPTS 830.6317 and OPPTS 830.6320) reports for the following two registrations containing the active ingredient Fipronil:

- Sergeant's Fipronil + Methoprene Squeeze-On for Dogs (EPA Registration No. 2517-134), and
- Sergeant's Fipronil Squeeze-On for Dogs (EPA Registration No. 2517 – 136).

In an October 31, 2011 letter to the Agency, Sergeant's stated its intention to submit the interim storage stability studies to the Agency upon completion. Following the Agency's conditional registration of these two products on November 4, 2010, the formulations were prepared and packaged into the commercial containers (plastic tubes). These samples were then sent to the CRO (contract research organization) that was contracted to perform the combined studies, as per the study guidelines. The lab received the samples and initiated the studies and the 6 - month analyses for both products have been completed. These results, which show the products are stable and there is no deterioration of the containers, are contained in the enclosed interim reports.

If you have any questions regarding this submission, please contact me at 402-938-7079.

Sincerely,



Kelly R. Hoskins
Manager of Technical Affairs
Enclosures

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Sergeant's Pet Care Products, Inc.
2625 South 158th Plaza
Omaha, NE 68130-1770

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

Interim Storage Stability and Corrosion Characteristics Reports for two registrations.

SUBMITTAL DATE:

November 17, 2011

Volume	Study Title	MRID No.
1	Product Chemistry Measurement of Storage Stability & Corrosion Characteristics of Sergeant's Fipronil + Methoprene Squeeze-On for Dogs (EPA Registration No. 2517-134)	48659901
2	Product Chemistry Measurement of Storage Stability & Corrosion Characteristics of Fipronil Animal Squeeze-On (EPA Registration No. 2517-136)	48659902

Confirmation of receipt by US EPA Document Processing Desk

USEPA Document Processing Desk

Date/Time

8/13

Sergeant's Master Label

29 Aug 2013 Mitigation
Information in [] is optional.

Version 13.1
Page 4 of 9

EPA No. 2517-134
EPA SAL 21 Feb 2012
Supersedes EPA Pending 27 Dec 2012

[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]
[Company name].]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[1][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-methoprene..... 8.80%

OTHER INGREDIENT: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

[0.023 fl oz (0.67 mL) applicators] [0.045 fl oz (1.34 mL) applicators]

[0.091 fl oz (2.68 mL) applicators] [0.136 fl oz (4.02 mL) applicators]

{END - FRONT PANEL}

BACK/SIDE PANEL

DOG SQUEEZE ON

FIPRONIL+METHOPRENE

[[Brand Name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

Material Sent for Data Extraction

Reg. # 2517-134

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☒ Notification⁴ Dated ~~2/17/2014~~ 3/13/2014

☐ New CSF(s) Dated _____

☐ Other: _____

☒ Decision #: 488559

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Melody Banks

Phone: 305 5413 Division: IB/kd

Date: 3/13/2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 13 2014

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Kelly R. Hoskins
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-1710

Subject: Label Notification(s) for Pesticide Registration 98-10

Dear Ms. Hoskins:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated for February 10, 2014 for:

Alternate Brand Names

Sergeant's® Frontier Gold Plus (Spot On) for Dogs
Sergeant's® Ectoadvance Plus (Spot On) for Dogs
Sentry Proline Plus (Spot On) for Dogs
Sentry® Frontier Gold Plus (Spot On) for Dogs
Sentry® Ectoadvance Plus (Spot On) for Dogs
PetArmor® Plus for dogs
Sergeant's® PetArmor® Plus for Dogs

The Registration Division (RD) has conducted a review of this request for applicability Under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

**EPA Registration Number: 2517-134 Sergeant's Fipronil + Methoprene Squeeze-On
For Dogs**

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Melody Banks on 703 305-5413 or via E-mail at banks.melody@epa.gov.

Sincerely,

Richard Gebken
Product Manager
Insecticide Branch
Registration Division (7504P)

Decision Seq: 488559 Action Code: 332,NOTIFICATION,,30



Decision Status

FFS Start Date:

Tentative Ind:

Start/Stop Clock

FQPA Clock:

Tracking

Due Date: 12-Mar-2014

75-Day Due Date:

Days Elapsed:

Create Resubmission

OPP Target Due Date:

21-Day Due Date:

FFS Original Decision:



FFS Letters

Negotiated Due Date:

45/90 Due Date:

Waiver Documentation

Registrant



Predecisional

Action Code History

Response Due Date:

Due Date:

Secondary Decision

Current Status: PENDING (13-Mar-2014)

☒ 75 Day Letters
 ☒ 45/90 Day Screen
 ☒ Primary Decisions
 ☒ Decision Milestone

☒ FFS Negotiated Due Dates
 ☒ OPP Target Due Date
 ☒ Decision Comments
 ☒ Payment
 ☒ Unmatched Payments

☒ Decision Ownership
 ☒ Receipts
 ☒ Data Package
 ☒ Reduced Risk
 ☒ Meetings & Milestones
 ☒ FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 2517-134 NA	Banks, Melody	2517-134	12-Mar-2014	PENDING

Viewing Record 1 of 1

Receipt for Section 3



S: 9475F1 Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 10

Product #: 2517-134 Product Name: SERGEANT'S FIPRONIL + METHOPRENE SOLUTION

Override#:

Me Too Section 3: 65331-5 Me Too Product Name: FRONTLINE PLUS FOR DOGS

Application Date: 10-Feb-2014

OPP Rec'd Date: 10-Feb-2014

Front End Date: 10-Feb-2014

Risk Manager Send Date: 10-Feb-2014

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Paper Label	

Fast Track: ☐

New Ingredient: ☐

View/Edit

Receipt Description:

Label Notification - ABNs (7)

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

332

Wendy

February 10, 2014

Richard Gebken
Product Manager 10
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Application for Pesticide Notification (Addition of Alternate Brand Name) for
Sergeant's Fipronil + Methoprene Squeeze-On for Dogs,
EPA Reg. No. 2517-134

Dear Mr. Gebken:

Sergeant's Pet Care Products, Inc. (Sergeant's, EPA Company No. 2517) is submitting a notification, as permitted under Pesticide Registration Notice 98-10, to add optional Alternate Brand Names to the end use registration Sergeant's Fipronil + Methoprene Squeeze-On for Dogs (EPA Reg. No. 2517-134), containing the active ingredients fipronil and s-methoprene.

The new optional alternate brand names are highlighted on one copy of the label, and please note that no other changes have been made to the EPA label recently accepted and stamped September 11, 2013. In support of this action the following documents are enclosed:

- 8570-1 Application for Pesticide Notification
- Product Master Label v14.1 dated 2/10/2014 (2 copies; one copy highlighted)

Please do not hesitate to contact me at 402-938-7079 or khoskins@sergeants.com if you have any questions or need further information.

Sincerely,



Kelly R. Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc.

Enclosures

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-134		2. EPA Product Manager Richard Gebken	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Fipronil + Methoprene Squeeze-On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-1710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name NOTIFICATION MAR 13 2014	
Section II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sec 12 and 14 of FIFRA. Please see cover letter for details. Label notification alternate brand names. Please see cover letter for details.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.023 fl oz, 0.045 fl oz, 0.091 fl oz, 0.136 fl oz	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1,2,3,4,5,6, 12,24 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify, Plastic Bag)
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.023 fl oz (0.67 ml), 0.045 fl oz (1.34 ml), 0.091 fl oz (2.68 ml), 0.136 fl oz (4.02 ml)	
5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Kelly R. Hoskins		Title Director of Regulatory Affairs	
		Telephone No. (Include Area Code) 402-938-7079	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: <i>Kelly R. Hoskins</i>		3. Title Director of Regulatory Affairs	
4. Typed Name: Kelly R. Hoskins		5. Date: 2/10/2014	

Sergeant's Master Label

10 Feb 2014 ABN Notification
Information in [] is optional.

Version 14.1
Page 1 of 9

EPA No. 2517-134
EPA SAL 9/11/2013

FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs:]

[Sergeant's® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sergeant's® Ectoadvance Plus (Spot On) for Dogs]

[Sergeant's® AdvanSpot Plus (Spot On) for Dogs]

[Sergeant's® PRONYL OTC™ PLUS for Dogs]

[SentryProline Plus (Spot On) for Dogs]

[SENTRY® FIPROGUARD™ PLUS for Dogs]

[SENTRY® AdvanSpot Plus (Spot On) for Dogs]

[Sentry® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sentry® Ectoadvance Plus (Spot On) for Dogs]

[PetArmor® Plus for dogs]

[Sergeant's® PetArmor® Plus for dogs]

NOTIFICATION

MAR 13 2014

[1.5cm x 1.5cm on final or as indicated]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR}

For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age {OR}

ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs] {OR}

ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-][to] 22 lbs

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

Sergeant's Master Label

10 Feb 2014 ABN Notification
Information in [] is optional.

Version 14.1
Page 2 of 9

EPA No. 2517-134
EPA SAL 9/11/2013

[Breaks the Flea Life Cycle [for up to three months]]
[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]
[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]
[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]
[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]
[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Use [Brand Name][This product] monthly to break the flea life cycle.]
[Use [Brand Name][This product] monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks], [and deer ticks] [for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]
[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If dog is a high risk for flea reinfestation a once month application may be needed]
[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle;
[With (S)-methoprene to Break Flea Life Cycle]
[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Prevents all stages of the flea life cycle from developing]
[Controls reinfestation of fleas for up to 3 months]
[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

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[All Others]

[For Dogs and Puppies 8 weeks of age or older]

[Can be used on puppies 8 weeks of age and older]

[Specially Formulated for Dogs and Puppies 8 weeks of age or older]

[For Dogs [4-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]

[Fast Acting] [Long Lasting]

[Convenient spot treatment]

[Easy to Use [Application]]

[Best if used year round!]

[For year-round protection, apply [Brand Name] monthly]

[(ICON Showing [4 week] [1 month] [30 day] Protection)]

[Apply monthly]

[Prevents reinfestation of listed pests for [4 weeks] [1 month]]

[Apply once every [4 weeks] [month] [30 days]!]

[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]

[Controls mites that may cause sarcoptic mange]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]

[[Free] Calendar Stickers Inside!]

[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]

[Fipronil (9.8%) + (S)-methoprene (8.8%)]

[Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)]

[FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*]

[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].]

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[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]
[Company name].]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[1][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil 9.80%

(S)-methoprene 8.80%

OTHER INGREDIENT:..... 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

[0.023 fl oz (0.67 mL) applicators] [0.045 fl oz (1.34 mL) applicators]

[0.091 fl oz (2.68 mL) applicators] [0.136 fl oz (4.02 mL) applicators]

{END - FRONT PANEL}

BACK /SIDE PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Brand Name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs. [including small dogs and puppies, 8 weeks or older]:

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

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{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs.

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs.

Apply one tube (2.68 mL)(0.091 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not use two tubes on dogs greater than 132 lbs

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box]
Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA] [U.S. Patent No. 5,567,429]
[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc. [BAR CODE AREA][Lot code]
Omaha, NE 68138-3710 EPA Reg. No. 2517-134
EPA Est. No. [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

DOG SQUEEZE ON
FIPRONIL+METHOPRENE

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Application Instructions] [Directions for Use]

How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Brand Name][This Product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[calendar stickers with [Brand Name] [This Product] [Place stickers on your calendar as a reminder to reapply [Brand Name] [This Product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]



























Sergeant's Master Label

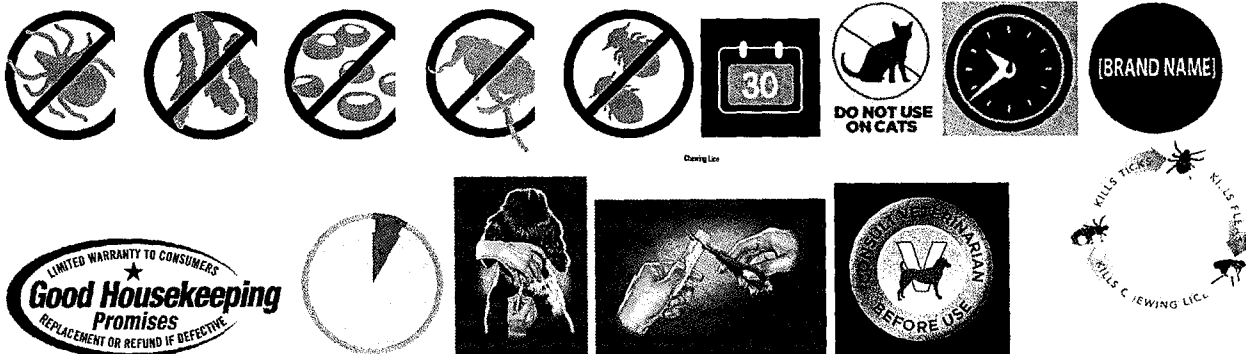
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[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	



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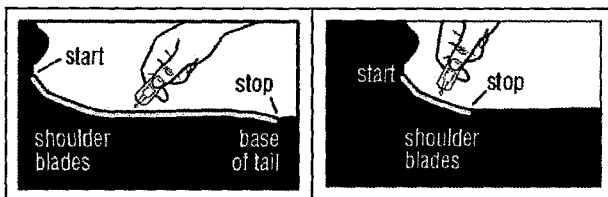
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[Flea life cycle diagram] [Flea Life Cycle]



{END - PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON
FIPRONIL+METHOPRENE

{Front Label}

{Back Label}

{Brand Name}

For Dogs [X-Y] lbs \geq 8 wks

fipronil 9.8%, s-methoprene 8.8%

0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)

0.136 fl oz {label code}



KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before using. Use scissors to open.

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{label code}

{END - TUBE/VIAL LABEL}

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs:]

[Sergeant's® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sergeant's® Ectoadvance Plus (Spot On) for Dogs]

[Sergeant's® AdvanSpot Plus (Spot On) for Dogs]

[Sergeant's® PRONYL OTC™ PLUS for Dogs]

[SentryProline Plus (Spot On) for Dogs]

[SENTRY® FIPROGUARD™ PLUS for Dogs]

[SENTRY® AdvanSpot Plus (Spot On) for Dogs]

[Sentry® FRONTIER GOLD Plus (Spot On) for Dogs]

[Sentry® Ectoadvance Plus (Spot On) for Dogs]

[PetArmor® Plus for dogs]

[Sergeant's® PetArmor® Plus for dogs]

[1.5cm x 1.5cm on final or as indicated]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR}

For use ONLY on dogs [1&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age {OR}

ONLY For Dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs] {OR}

ONLY For Dogs & Puppies 8 weeks or older [1&][and] 4[-] [to] 22 lbs

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [1&] [and] Tick Control for Dogs [1&] [and] Puppies 8 weeks old [1&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [1&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [1&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [1&] [and] [Mosquitoes]]

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[Breaks the Flea Life Cycle [for up to three months]]
[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]
[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]
[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]
[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]
[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Use [Brand Name][This product] monthly to break the flea life cycle.]
[Use [Brand Name][This product] monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks],[,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]
[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If dog is a high risk for flea reinfestation a once month application may be needed]
[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Prevents all stages of the flea life cycle from developing]
[Controls reinfestation of fleas for up to 3 months]
[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

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[All Others]

[For Dogs and Puppies 8 weeks of age or older]
[Can be used on puppies 8 weeks of age and older]
[Specially Formulated for Dogs and Puppies 8 weeks of age or older]
[For Dogs [4-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]
[Fast Acting] [Long Lasting]
[Convenient spot treatment]
[Easy to Use [Application]]
[Best if used year round!]
[For year-round protection, apply [Brand Name] monthly]
[(ICON Showing [4 week] [1 month] [30 day] Protection)]
[Apply monthly]
[Prevents reinfestation of listed pests for [4 weeks] [1 month]]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Controls mites that may cause sarcoptic mange]
[Waterproof]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]
[[Free] Calendar Stickers Inside!]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]
[Fipronil (9.8%) + (S)-methoprene (8.8%)]
[Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*]
[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].]

Sergeant's Master Label

10 Feb 2014 ABN Notification
Information in [] is optional.

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[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]
[Company name].]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[1][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil 9.80%

(S)-methoprene 8.80%

OTHER INGREDIENT:..... 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

[0.023 fl oz (0.67 mL) applicators] [0.045 fl oz (1.34 mL) applicators]

[0.091 fl oz (2.68 mL) applicators] [0.136 fl oz (4.02 mL) applicators]

{END - FRONT PANEL}

BACK /SIDE PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Brand Name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs. [including small dogs and puppies, 8 weeks or older]:

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

Sergeant's Master Label

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{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs.

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs.

Apply one tube (2.68 mL)(0.091 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not use two tubes on dogs greater than 132 lbs

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box]
Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA] [U.S. Patent No. 5,567,429]
[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc. [BAR CODE AREA][Lot code]
Omaha, NE 68138-3710 EPA Reg. No. 2517-134
EPA Est. No. [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

Sergeant's Master Label

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Information in [] is optional.

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Application Instructions] [Directions for Use]

How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Brand Name][This Product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[calendar stickers with [Brand Name] [This Product] [Place stickers on your calendar as a reminder to reapply [Brand Name] [This Product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]



























Sergeant's Master Label

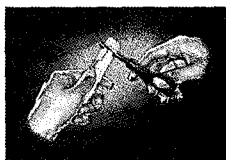
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[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	

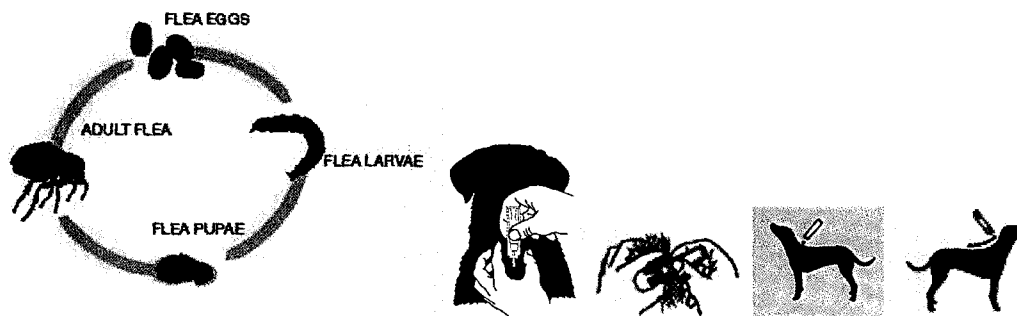


Sergeant's Master Label

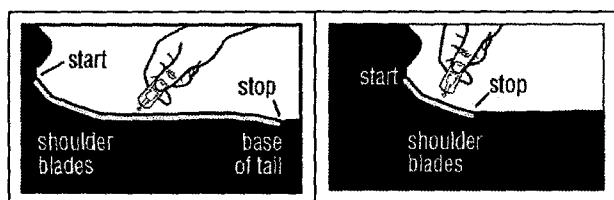
10 Feb 2014 ABN Notification
Information in [] is optional.

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[Flea life cycle diagram] [Flea Life Cycle]



{END - PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

{Front Label}

{Back Label}

<p>{Brand Name} For Dogs [X-Y] lbs \geq 8 wks fipronil 9.8%, s-methoprene 8.8% 0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-134 {label code}</p>
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{END - TUBE/VIAL LABEL}



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 7 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Kelli A. Ten Hulzen
Regulatory Associate
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138

Subject: Notification: Alternate Brand Names (ABNs)
EPA Registration Number: 2517-134
Product Name: Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
Submission Date: December 16, 2013
Decision Number: 486964

Dear Ms. Ten Hulzen:

The Agency is in receipt of your Application for Pesticide Notification dated December 16, 2013 for EPA Reg. No. 2517-134. The Registration Division has conducted a review of this request for its applicability under the Pesticide Registration Notice (PRN) 98-10, and finds that the proposed alternate brand names are **not acceptable** because at least one of the ABNs you proposed is already an ABN for another Sergeant's product.

Please note that PRNs are provided as guidance and they are not considered regulation by the Agency, and that the Registration Division reserves the right to make the determination regarding acceptability of any Notification submission. The Registration Division has determined that this action is **not acceptable**.

If you have any questions, please call me directly at 703-305-6701 or Kristen Hendricks of my staff at 703-308-0308.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Insecticide Branch PM 10 Team Leader
Registration Division (7505P)
Office of Pesticide Programs

Decision Information for 2517-134



Decision Seq: 486964 Action Code: 332,NOTIFICATION;30

Decision Status

FFS Start Date: Tentative Ind: No Start/Stop Clock FQPA Clock:

Tracking

Due Date: 25-Jan-2014 75-Day Due Date: Days Elapsed:

Create Resubmission

OPP Target Due Date: 21-Day Due Date: FFS Original Decision:

FFS Letters

Negotiated Due Date: 45/90 Due Date:

Waiver Documentation

Registrant: Predecisional Due Date:

Action Code History

Response Due Date: Current Status: PENDING (23-Jan-2014)

Secondary Decision

75 Day Letters 45/90 Day Screen Primary Decisions Decision Milestone

FFS Negotiated Due Dates OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 945421	Hendricks, Kristen	2517-134	25-Jan-2014	PENDING

Submission to add ABNs.

↳ Alternate Brand Names

Viewing Record 1 of 1

New ABNs
rejected

Receipt for Section 3

S: 945421

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Company: 2517 SERGEANT'S PET CARE PRODUCTS, INC.



Risk Manager: Registration Division, Risk Management Team 10

Product #: 2517-134 Product Name: SERGEANT'S FIPRONIL + METHOPRENE SQUI

Override#:

Me Too

Section3: 55331-5

Me Too

Product Name: FRONTLINE PLUS FOR DOGS

Application Date: 16-Dec-2013



OPP Rec'd Date: 26-Dec-2013



Front End Date: 26-Dec-2013



Risk Manager Send Date: 26-Dec-2013



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
<div style="text-align: center;"> </div>	

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label Notification - ABNs (5)

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

View/Edit

December 16, 2013

Richard Gebken, PM10
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Re: Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Registration # 2517-134
Notification of Additional Alternate Brand Names per PR Notice 98-10

Dear Mr. Gebken:

Please consider this Notification of additional new Alternate Brand Names to the Sergeant's Pet Care Products, Inc. Master Label for Sergeant's Fipronil + Methoprene Squeeze-On for Dogs, EPA Registration Number 2517-134. In support of this Notification please find attached the following:

1. Application for Pesticide Registration, EPA Form 8570-1

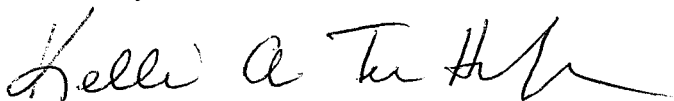
As provided by PR Notice 98-10, Sergeant's is requesting Agency approval of the following new Alternate Brand Names for the 2517-134 11September2013 Amendment:

1. SENTRY® FIPROGUARD® PLUS for Dogs and Puppies
2. PetArmor® Plus for Dogs
3. Sergeant's PetArmor® Plus for Dogs
4. PetArmor® Plus for Dogs & Puppies
5. Sergeant's PetArmor® Plus for Dogs & Puppies

No other changes are being requested to the 11September2013 Amendment.

Thank you for your assistance. Please contact me at 402-938-7065, if there are any questions concerning this submission.

Sincerely,



Kelli A. Ten Hulzen
Regulatory Associate

Enclosures

EPA
 United States
Environmental Protection Agency
 Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2517-134	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeants Fipronil + Methoprene Squeeze-On for Dogs	5. PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification adds the following Alternate Brand Names to the label for this product: SENTRY® FIPROGUARD® PLUS for Dogs and Puppies, PetArmor® Plus for Dogs, Sergeant's PetArmor® Plus for Dogs & Puppies, Sergeant's PetArmor® Plus for Dogs & Puppies. This Notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 USC Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10, and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will Be Packaged In:														
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag											
*Certification must be submitted		<table border="1"> <tr> <th>If "Yes"</th> <th>No. per Container</th> </tr> <tr> <td>Unit Packaging wgt. 0.023 fl oz (0.67 mL)</td> <td rowspan="4">1, 3, 6, 12 & multiple vials</td> </tr> <tr> <td>0.045 fl oz (1.34 mL)</td> </tr> <tr> <td>0.091 fl oz (2.68 mL)</td> </tr> <tr> <td>0.136 fl oz (4.02 mL)</td> </tr> </table>	If "Yes"	No. per Container	Unit Packaging wgt. 0.023 fl oz (0.67 mL)	1, 3, 6, 12 & multiple vials	0.045 fl oz (1.34 mL)	0.091 fl oz (2.68 mL)	0.136 fl oz (4.02 mL)	<table border="1"> <tr> <th>If "Yes"</th> <th>No. per Container</th> </tr> <tr> <td>Package wgt.</td> <td></td> </tr> </table>	If "Yes"	No. per Container	Package wgt.	
If "Yes"	No. per Container													
Unit Packaging wgt. 0.023 fl oz (0.67 mL)	1, 3, 6, 12 & multiple vials													
0.045 fl oz (1.34 mL)														
0.091 fl oz (2.68 mL)														
0.136 fl oz (4.02 mL)														
If "Yes"	No. per Container													
Package wgt.														
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 0.023 fl oz (0.67 mL), 0.045 fl oz (1.34 mL), 0.091 fl oz (2.68 mL), 0.136 fl oz (4.02 mL)		5. Location of Label Directions <input type="checkbox"/> On Can <input checked="" type="checkbox"/> On Labeling accompanying product											
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled														

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kelli A. Ten Hulzen	Title Regulatory Associate	Telephone No. (Include Area Code) 402-338-7065
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Late Application Received (Stamped)
2. Signature BY: <i>Kelli A. Ten Hulzen</i>	3. Title Regulatory Associate	
4. Typed Name:	5. Date: 16DEC13	

10/10/10

10/10/10

10/10/10

10/10/10

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10/10/10

10/10/10

10/10/10

10/10/10

2517-134

Currently, the Active and Alternate Brand Names (ABNs) for **2517-134** in PPLS are:

SERGEANT'S FIPRONIL + METHOPRENE SQUEEZE-ON FOR DOGS	Active
(SERGEANT'S) (SENTRY) VETSPOT PLUS (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) FRONTIER GOLD (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) ECTOADVANCE (SPOT ON) FOR DOGS	Alternate
SENTRYPROLINE (SPOT ON) FOR DOGS	Alternate
SENTRY VET (SPOT ON) FOR DOGS	Alternate
[SENTRY] FIPROGUARD PLUS FOR DOGS	Alternate
[SERGEANT'S] PRONYL OTC PLUS FOR DOGS	Alternate

Sergeant's would like to add the following alternate brand names (ABNs):

- **SENTRY FIPROGUARD PLUS for Dogs and Puppies**
 - This ABN appears to be OK. Please note that this product already has an ABN "[SENTRY] FIPROGUARD PLUS FOR DOGS".
- **PetArmor Plus for Dogs**
 - The following ABNs are already registered for product number 2517-141:
 - **PETARMOR PLUS FOR DOGS**
 - PETARMOR PLUS II FOR DOGS
 - The following ABNs are already registered for product number 2517-143:
 - PETARMOR MAX FOR DOGS
 - PETARMOR PRO ADVANCED FOR DOGS
 - "PetArmor Plus for Dogs" was the registration name for a formerly registered pesticide:
 - Registration #:** 86230-4-85495
 - Registration Name:** PETARMOR PLUS FOR DOGS
 - Company:** 85495 - FIDOPHARM, INC.
 - Current Status:** Inactive - Cancelled (17-Oct-2011)
 - Restricted Use:** No

- **Sergeant's PetArmor Plus for Dogs**

- The following ABNs are already registered for product number 2517-141:
 - SERGEANT'S PETARMOR OTC PLUS FOR DOGS
 - SERGEANT'S PETARMOR OTC II FOR DOGS
 - **SERGEANT'S PETARMOR PLUS FOR DOGS**
 - SERGEANT'S PETARMOR PLUS II FOR DOGS
- The following ABNs are already registered for product number 2517-143:
 - SERGEANT'S PETARMOR MAX FOR DOGS
 - SERGEANT'S PETARMOR PRO ADVANCED FOR DOGS
 - SERGEANT'S PETARMOR PRO ADVANCED TICKS FOR DOGS

- **PetArmor Plus for Dogs & Puppies**

- This ABN appears to be OK.

- **Sergeant's PetArmor Plus for Dogs & Puppies**

- This ABN appears to be OK.

2517-14

Registration Name Information

Name	Status
SERGEANT'S FIPRONIL + METHOPRENE SQUEEZE-ON FOR DOGS	Active
(SERGEANT'S) (SENTRY) VETSPOT PLUS (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) FRONTIER GOLD (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) ECTOADVANCE (SPOT ON) FOR DOGS	Alternate
SENTRYPROLINE (SPOT ON) FOR DOGS	Alternate
SENTRY VET (SPOT ON) FOR DOGS	Alternate
[SENTRY] FIPROGUARD PLUS FOR DOGS	Alternate
[SERGEANT'S] PRONYL OTC PLUS FOR DOGS	Alternate
Total Rows: 8	

Close

Print

Registration Name Information

Name	Status
SERGEANT'S FIPRONIL SQUEEZE-ON FOR DOGS	Active
(SERGEANT'S) (SENTRY) (ADVANSPO) (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) VETSPOT (SPOT ON) FOR DOGS	Inactive
(SERGEANT'S) (SENTRY) FRONTIER GOLD (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) ECTOADVANCE (SPOT ON) FOR DOGS	Alternate
SENTRYVET (SPOT ON) FOR DOGS	Alternate
[SENTRY] FIPROGUARD FOR DOGS	Alternate
[SERGEANT'S] PRONYL OTC FOR DOGS	Alternate
SENTRYPROLINE (SPOT ON) FOR DOGS	Alternate
FIPROSPOT (TOPICAL) FOR DOGS (AND PUPPIES)	Alternate
ECTOSPOT (TOPICAL) FOR DOGS (AND PUPPIES)	Alternate
ECTOPRONIL (TOPICAL) FOR DOGS (AND PUPPIES)	Alternate
ECTOADVANCE (TOPICAL) FOR DOGS (AND PUPPIES)	Alternate
F-PRONIL (TOPICAL) FOR DOGS (AND PUPPIES)	Alternate
MERIDIAN ANIMAL HEALTH	Alternate
Total Rows: 15	

Close**Print**

Registration Name Information

Name	Status
SERGEANT'S FIPRONIL + NYLAR SQUEEZE-ON FOR DOGS	Active
SERGEANT'S PETARMOR OTC PLUS FOR DOGS	Alternate
SERGEANT'S PET ARMOR OTC II FOR DOGS	Alternate
SERGEANT'S FAST ACT OTC PLUS FOR DOGS	Alternate
SERGEANT'S FAST ACT OTC II FOR DOGS	Alternate
FAST ACT OTC PLUS FOR DOGS	Alternate
FAST ACT OTC II FOR DOGS	Alternate
PETARMOR PLUS FOR DOGS	Alternate
SERGEANT'S PETARMOR PLUS FOR DOGS	Alternate
PETARMOR PLUS II FOR DOGS	Alternate
SERGEANT'S PET ARMOR PLUS II FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) FRONTIER GOLD (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) ECTOADVANCE (SPOT ON) FOR DOGS	Alternate
SERGEANT'S PRONYL OTC II FOR DOGS	Alternate
SERGEANT'S PRONYL OTC PLUS FOR DOGS	Alternate
SENTRY FIPROGUARD II FOR DOGS	Alternate
SENTRY FIPROGUARD PLUS FOR DOGS	Alternate
SENTRY ECTOADVANCE FOR DOGS	Alternate
SENTRY ECTOADVANCE SPOT ON FOR DOGS	Alternate
SERGEANT'S ECTOADVANCE FOR DOGS	Alternate
SERGEANT'S ECTOADVANCE SPOT ON FOR DOGS	Alternate
SENTRY FRONTIER GOLD SPOT ON FOR DOGS	Alternate
SENTRY FRONTIER GOLD FOR DOGS	Alternate
SERGEANT'S FRONTIER GOLD SPOT ON FOR DOGS	Alternate
SERGEANT'S FRONTIER GOLD FOR DOGS	Alternate
Total Rows: 25	

Close

Print

Registration Name Information

Name	Status
SERGEANT'S FIPRONIL + CYPHENOTHHRIN + NYLAR SQUEEZE-ON FOR DOGS	Active
PETARMOR MAX FOR DOGS	Alternate
SERGEANT'S PETARMOR MAX FOR DOGS	Alternate
PETARMOR PRO ADVANCED FOR DOGS	Alternate
SERGEANT'S PETARMOR PRO ADVANCED FOR DOGS	Alternate
PETARMOR PRO ADVANCED TICKS FOR DOGS	Alternate
SERGEANT'S PETARMOR PRO ADVANCED TICKS FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) FRONTIER GOLD (SPOT ON) FOR DOGS	Alternate
(SERGEANT'S) (SENTRY) ECTOADVANCE (SPOT ON) FOR DOGS	Alternate
Total Rows: 9	

Material Sent for Data Extraction

Reg. # 2517-134

Description: AMENDMENT - SPOT ON MITIGATION

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated 9/11/2013

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 478139

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: KATHY KUEHL

Phone: 308.8172 Division: PRD

Date: 9/11/2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Kelly R. Hoskins
Director of Regulatory Affairs
Sergeant's Pet Care Products, Inc.
2625 South 158th Plaza
Omaha, NE 68130-1770

SEP 11 2013

Subject: Sergeant's submissions implementing label changes to pet spot-on products
EPA Decision Nos. 478139, 478335, 478142, and 478144

- Sergeant's Fipronil Squeeze-On for Dogs
EPA Reg. No. 2517-134
- Sergeant's Fipronil + Methoprene Spot-On for Cats
EPA Reg. No. 2517-135
- Sergeant's Fipronil + Methoprene Squeeze-on for Dogs
EPA Reg. No. 2517-136
- Sergeant's Fipronil Spot-On for Cats
EPA Reg. No. 2517-137

Dear Mr. Hoskins,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action.

EPA also received your December 21 2012 request to replace the conditional time-limited registrations with unconditional registrations. At this time, EPA does not have enough information to warrant the removal of these conditions of registration. If Sergeant's wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for each product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you may remember, the Agency included this time limitation as a condition of registration for your products to allow for the post-market surveillance of these products. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g.; tables, charts, information on stewardship activities, etc...):

- A summary and analysis of the incidents received associated with these products, including information on the following:

- A comprehensive analysis of incident rates per doses distributed;
- An analysis of historical incident trends since the products' release into the marketplace;
- An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If these products are also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day, fast-track submission in order to allow the EPA enough time to fully evaluate the information provided. After receiving these submissions, the EPA will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

In the interim, the time-limited registrations for these products are extended two years from the date of this letter. If registration extension requests are not received prior to that date, the registration of these products will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with any of these products, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot #

Where purchased: internet, store, veterinarian

Active Ingredient(s)

Weight range for product

Date on which incident occurred. (mm/dd/yyyy)

State in which the incident occurred. (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify)

Breed: (as reported by pet owner)

Age: months or years

Sex: M, F, or neutered

Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.

- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

Stamped copies of the labels are enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken", with a stylized flourish at the end.

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Labels stamped "Accepted"

Sergeant's Master Label

29 Aug 2013 Mitigation
Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs:]

[Sergeant's® FRONTIER GOLD (Spot On) for Dogs]

[Sergeant's® Ectoadvance (Spot On) for Dogs]

[Sergeant's® AdvanSpot Plus (Spot On) for Dogs]

[Sergeant's® PRONYL OTC™ PLUS for Dogs]

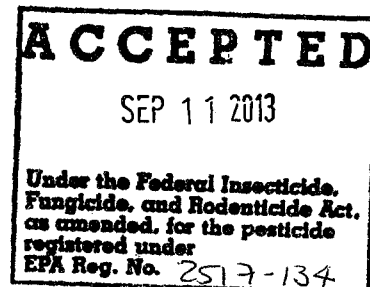
[SentryProline (Spot On) for Dogs]

[SENTRY® FIPROGUARD™ PLUS for Dogs]

[SENTRY® AdvanSpot Plus (Spot On) for Dogs]

[Sentry® FRONTIER GOLD (Spot On) for Dogs]

[Sentry® Ectoadvance (Spot On) for Dogs]



[1.5cm x 1.5cm on final or as indicated]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]



[For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]]

[For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age]

OR

[ONLY For Dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]]

[ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-] [to] 22 lbs]

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

Sergeant's Master Label

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Information in [] is optional.

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[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]
[Monthly flea, tick, [mosquito] and chewing lice protection]
[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]
[[Seven] [7] [Six] [6][Five[5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, flea eggs, [&][and]flea larvae [&] [and] prevent the development of flea pupae]]
[[Six] [6] [Five] [5][Four][4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes,] chewing lice, [&][and]flea eggs [&] [and] flea larvae]
[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]
[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]
[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]
[Use [Brand Name][This product] monthly to break the flea life cycle.]
[Use [Brand Name][This product] monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks],[,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]
[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If dog is a high risk for flea reinfestation a once month application may be needed]
[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Prevents all stages of the flea life cycle from developing]
[Controls reinfestation of fleas for up to 3 months]
[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

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[All Others]

[For Dogs and Puppies 8 weeks of age or older]
[Can be used on puppies 8 weeks of age and older]
[Specially Formulated for Dogs and Puppies 8 weeks of age or older]
[For Dogs [4-22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]
[Fast Acting] [Long Lasting]
[Convenient spot treatment]
[Easy to Use [Application]]
[Best if used year round!]
[For year-round protection, apply [Brand Name] monthly]
[(ICON Showing [4 week] [1 month] [30 day] Protection)]
[Apply monthly]
[Prevents reinfestation of listed pests for [4 weeks] [1 month]]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Controls mites that may cause sarcoptic mange]
[Waterproof]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]
[[Free] Calendar Stickers Inside!]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]
[Fipronil (9.8%) + (S)-methoprene (8.8%)]
[Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*]
[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].]

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[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®]
[Company name].]

[[Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[[1][2][3][4][5][6][12][24] Applications]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]]

[Stops existing infestation and prevents establishment of additional infestation of listed pests]

[Lift [here] for more information]

ACTIVE INGREDIENTS:

Fipronil..... 9.80%

(S)-methoprene..... 8.80%

OTHER INGREDIENT: 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

See [Back][or][Side] [Label[s]] [Panel[s]] for Additional Precautionary Statements

Net Contents: X fl oz [Y – 0.0xx fl oz (x mL) applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]

[0.023 fl oz (0.67 mL) applicators] [0.045 fl oz (1.34 mL) applicators]

[0.091 fl oz (2.68 mL) applicators] [0.136 fl oz (4.02 mL) applicators]

{END - FRONT PANEL}

BACK /SIDE PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Brand Name][This product] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Brand Name][This product] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product.

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FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on cats, rabbits or animals other than dogs. Do not allow your dog to ingest this product. Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs. Use entire contents of tube vial on each dog. [Do not split one tube between dogs.] Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-781-4738. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your dog and continue to monitor your dog for the next 24 hours.

[1.5cm x 1.5cm on final or as indicated]



DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Only For Dogs Weighing 4 [-] [to] 22 lbs. Do not apply to dogs weighing less than 4 lbs.

[including small dogs and puppies, 8 weeks or older]:

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

Sergeant's Master Label

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{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Only For Dogs Weighing 23 [-] [to] 44 lbs.

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Only For Dogs Weighing 45 [-] [to] 88 lbs.

Apply one tube (2.68 mL)(0.091 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Only For Dogs Weighing 89 [-] [to] 132 lbs. Do not use two tubes on dogs greater than 132 lbs

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.]
[as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [Brand Name] [this product] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [Brand Name] [this product] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [Brand Name] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY] Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 [Coupon(s) inside or on outside of box]
Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA] [U.S. Patent No. 5,567,429]

Sergeant's Master Label

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Information in [] is optional.

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[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-134
EPA Est. No. [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Application Instructions] [Directions for Use]

How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after [treatment] [application] to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

[Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Brand Name][This Product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[calendar stickers with [Brand Name] [This Product] [Place stickers on your calendar as a reminder to reapply [Brand Name] [This Product] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][This Product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]























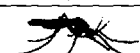



Sergeant's Master Label

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[Optional graphics below may or may not appear anywhere on finished label]

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	



Sergeant's Master Label

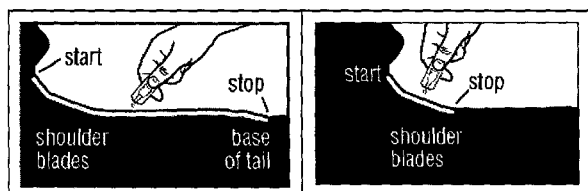
29 Aug 2013 Mitigation
Information in [] is optional.

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[Flea life cycle diagram] [Flea Life Cycle]




{END - PACKAGE COPY}

TUBE/VIAL LABEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

{Front Label}

{Back Label}

<p>{Brand Name} For Dogs [X-Y] lbs ≥8 wks fipronil 9.8%, s-methoprene 8.8% 0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz {label code}</p>	<p> KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 2517-134 {label code}</p>
--	--

{END - TUBE/VIAL LABEL}

Keller, Kaitlin

From: Mary Hunt [mhunt@exponent.com]
Sent: Thursday, August 29, 2013 8:41 PM
To: Keller, Kaitlin; James Messina
Cc: KHoskins@SERGEANTS.com
Subject: RE: Sergeant's Dog Label Language
Attachments: 2517-136 Mitigation v13 1 8-29-13.pdf; 2517-134 Mitigation v13 1 8-29-13.pdf

Hi, Kaitlin,

Per the email chain below, please see the attached Sergeant's dog labels for 2517-134 and 2517-136. The only revision in the Master Labels is the replacement of "Do not use on puppies under 8 weeks of age or less than 4 lbs." with "Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs." in the paragraph immediately under Directions for Use.

Please call me at 202-549-9761 if you have any questions.

You have a good weekend, too!

Mary

From: Keller, Kaitlin [<mailto:Keller.Kaitlin@epa.gov>]
Sent: Thursday, August 29, 2013 5:09 PM
To: James Messina
Cc: Mary Hunt; KHoskins@SERGEANTS.com
Subject: RE: Sergeant's Dog Label Language

Jim,

Yes this change is acceptable. I agree that having just 4 lbs as the minimum weight on all package sizes could be confusing to consuming. Please resend the dog labels with this change and I should be able to have the final review and labels stamped next week.

Have a good weekend,
Kaitlin

From: James Messina [<mailto:jmessina@exponent.com>]
Sent: Thursday, August 29, 2013 4:41 PM
To: Keller, Kaitlin
Cc: Mary Hunt; KHoskins@SERGEANTS.com
Subject: Sergeant's Dog Label Language

Kaitlin,

As a follow-up to our call today, we would like to revise the following text on the two pending Sergeant's dog labels:

Page 5 of 2517-136 "Do not use on puppies under 8 weeks of age or less than 4 lbs."

We propose to change it to the following:

"Do not use on puppies under 8 weeks of age or less than [4][23][45][89] lbs."

We list the language as optional but will include one of the weights to match the lower weight of the package. We believe that having the same lower weight will reduce potential miss-use of the product on a dog that is too small for the larger application sizes.

Please let me know if you agree and we will resend the Sergeant's dog labels with the change above (note no other changes will be made). We look forward to hearing from you.

Best Regards,

James Messina
Principal Regulatory Consultant
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036
202-772-4932
202-772-4979 fax
301-908-1181 cell

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Keller, Kaitlin

From: Mary Hunt [mhunt@exponent.com]
Sent: Monday, August 26, 2013 9:31 AM
To: Keller, Kaitlin
Cc: Gebken, Richard; James Messina
Subject: Final Mitigation Label Reg. 2517-134
Attachments: 2517-134 Mitigation v13 1 8-23-13.pdf

Hi, Kaitlin,

Attached please find the final mitigation label for Sergeant's Pet Care Products, Inc., EPA Reg. No. 2517-134, Sergeant's Fipronil + Methoprene Squeeze-On for Dogs.

Per our discussion Thursday last week, the acceptable comparative claims have been included on the label. However, the following claims have been removed from the label:

[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients [used][found] in leading [parasitocides][flea and tick prevention].]

[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient [used][found] in leading [parasitocides][flea and tick prevention].]

Also, per earlier email discussions, we have revised the front panel required text to include the age restriction for puppies:

[For use ONLY on dogs [23[-] [to] 44 lbs] [45[-] [to] 88 lbs] [89[-] [to] 132 lbs]]

[For use ONLY on dogs [[&][and] puppies 4[-] [to] 22 lbs and over 8 weeks of age]

(OR)

[ONLY For Dogs [23[-][to] 44 lbs] [45[-][to] 88 lbs] [89[-] [to] 132 lbs]]

[ONLY For Dogs & Puppies 8 weeks or older [&][and] 4[-][to] 22 lbs]

Note that w/w has been removed from the active ingredients percent on the applicator/tube label; for example, fipronil 9.8% ~~w/w~~.

No other changes have been made to the last draft label you reviewed on 8-05-2013 (and emailed to you on 7/30/2013). I did not highlight the changes made to the label and listed above. Please let me know if you need a highlighted copy.

This label supersedes earlier versions of mitigation labels including the version (v12.1) emailed to the Agency on 1/02/2013.

Thank you again for all of your help, and do not hesitate to call me at 202-549-9761 if you have any questions.
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

E^xponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

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contents of this confidential information is strictly prohibited. If you have received this communication in error, please destroy it immediately and notify the sender by telephone. Thank you

Keller, Kaitlin

From: Mary Hunt [mhunt@exponent.com]
Sent: Thursday, August 22, 2013 12:53 PM
To: Keller, Kaitlin
Cc: Gebken, Richard; James Messina
Subject: RE: Sergeant's (EPA Co. No. 2517) Mitigation Labels

Hi, Kaitlin,

Thank you for your email last week dated 8/15/2013. Your feedback is appreciated. However, I understand that the guidance only shows an example of unacceptable font styles i.e. "different point size, different font color, different font type." It does not appear that the guidance was suggesting that there is only one acceptable comparative statement.

Please note that I have also found some comparative claims that already appear on PPLS EPA stamped accepted labels as follows:

Compare to Frontline Plus same active ingredient.

This product is not manufactured or distributed by Merial, the makers of Frontline Plus. EPA Reg. No. 85495-2

Compare to Frontline Top Spot for Dogs. EPA Reg. No. 86230-2

[Contains Fipronil the [same] active ingredient used in Frontline brand products]*

[[Brand name] is not manufactured by or distributed by Merial. Frontline is a registered trademark of Merial.]EPA Reg. No. 53883-312*

I appreciate your concern regarding [brand name] being too open-ended. So, would the following examples below be acceptable in place of [brand name] in these claims? Or can you please suggest acceptable nomenclature for [brand name]?

For fipronil only claims, please see below [FRONTLINE® Top Spot® for Dogs (or any ABN)]:

[Contains [the] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient.*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]

[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient [used][found] in leading [parasiticides][flea and tick prevention].]

[[Brand Name] [products] [This product] contains(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[Brand Name] [products] [This product] contains(s) fipronil, compared to [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)][FRONTLINE® brand products].]

[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®] [Company name].]

Similarly, please see below the fipronil/methoprene comparative claims:

[Contains [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]

[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredient(s).*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient fipronil.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [an] [same] active ingredient (S)-Methoprene.*]
[Compare to [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products], contains [the] [same] active ingredients fipronil and (S)-Methoprene.*]
[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient [used][found] in leading [parasitocides][flea and tick prevention].]
[[Brand Name] [products] [This product] contain(s) fipronil, [the] [an] [same] active ingredient used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil, compared to [the] [an] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients [used][found] in leading [parasitocides][flea and tick prevention].]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, [the] [same] active ingredients used in [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[Brand Name] [products] [This product] contain(s) fipronil and (S)-Methoprene, compared to [the] [same] active ingredient(s) used in [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].*]
[[*][Brand Name][This product] is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE® Top Spot® for Dogs (or any ABN)] [FRONTLINE® Plus for Dogs (or any ABN)] [FRONTLINE® brand products].]
[[Brand Name][This product][Frontline®] [Frontline® TopSpot®] is a registered trademark of [Merial®] [Company name].]

Kaitlin, thank you for your help. Please do not hesitate to call me at 202-549-9761 with any questions.

Thank you,
Mary

From: Keller, Kaitlin [<mailto:Keller.Kaitlin@epa.gov>]
Sent: Thursday, August 15, 2013 1:40 PM
To: Mary Hunt
Cc: James Messina; Gebken, Richard
Subject: RE: Sergeant's (EPA Co. No. 2517) Mitigation Labels

Mary,

The proposed front panel age/weight statements are okay, the 8 week statement doesn't need to be on the larger sizes. Regarding the comparative claims, the specific product name needs to be included, we can't allow it to be open-ended as suggested below with [brand name]. The me-too guidance specifically refers to a product brand name in each example, it does not allow for comparison to a brand of products. Therefore, as an example, the only acceptable claim for 2517-136 would be:

[Contains fipronil, the same active ingredient used in FRONTLINE® Plus for Dogs.*]

Please let me know if you have any additional questions. I'll be out of the office tomorrow but back in on Monday.

Regards,
Kaitlin

Keller, Kaitlin

From: Mary Hunt [mhunt@exponent.com]
Sent: Tuesday, July 30, 2013 2:42 PM
To: Keller, Kaitlin
Cc: James Messina; Gebken, Richard
Subject: Sergeant's (EPA Co. No. 2517) Mitigation Labels
Attachments: 2517-134 Mitigation Draft v13 1.pdf; 2517-135 Mitigation Draft v13 2.pdf; 2517-136 Mitigation Draft v13 1.pdf; 2517-137 Mitigation Draft v13 2.pdf

Hi, Kaitlin,

On behalf of our client, Sergeant's Pet Care Products, Inc. (EPA Company No. 2517), please see the attached, revised labels submitted to meet Mitigation Measures outlined by the Agency for pet spot-on products for the following registrations:

2517-134 Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
2517-135 Sergeant's Fipronil + S-Methoprene Spot On for Cats
2517-136 Sergeant's Fipronil Squeeze-On for Dogs
2517-137 Sergeant's Fipronil Spot On for Cats

Kaitlin, these labels were prepared after the conference call Jim and I had with you and Richard on July 1st regarding the comments made on the 2517-133 label, and the most recent mitigation text agreed on during the call are [REDACTED].

Once the Agency finds the attached labels acceptable and meeting the mitigation requirements, they will be used as templates in order to have standard mitigation language among the Sergeant's spot-on product master labels. I think once we have a template, revising the other labels to meet "standardized mitigation text" should be a quick and straight forward process.

Please note that other minor revisions have been included on this label and are highlighted in yellow. These revisions are mostly "housekeeping" type changes.

Please let me know if you have any difficulty opening these files or if you need further information.

Thank you for your help,
Mary

Mary McKinney Hunt

Managing Regulatory Consultant

E^xponent[®], Inc

1150 Connecticut Avenue, Suite 1100 | Washington, DC 20036 |

p: 202.549.9761 | e-mail: mhunt@exponent.com | web: www.exponent.com

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 21, 2012

James B. Messina,
Principal Regulatory Consultant
(Authorized Agent for Sergeant's Pet Care Products, Inc.)
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Subject: Revise CRP labeling (Net Content, Opening and directions).

- Sergeant's Fipronil Squeeze-On for Dogs
EPA Reg. No. 2517-136
- Sergeant's Fipronil + Methoprene Squeeze-On for Dogs
EPA Reg. No. 2517-134
- Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs
EPA Reg. No. 2517-140
- Sergeant's Fipronil + Nylar Squeeze-On for Dogs
EPA Reg. No. 2517-141
- Sergeant's Fipronil + Cyphenothrin + Methoprene Squeeze-On for Dogs
EPA Reg. No. 2517-142
- Sergeant's Fipronil + Cyphenothrin + NyJar Squeeze-On for Dogs
EPA Reg. No. 2517-143

Applications dated September 26, 2011

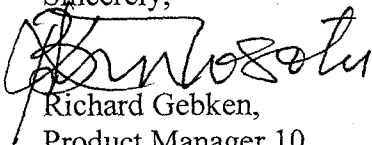
Dear Mr. Messina:

The above referenced labeling for each of the subject products, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable:

Please note that we have approved the amended labels for these products with the understanding that they are consistent with the Agency's previously stamped accepted ones; and other than the revisions stated in your applications (dated September 26, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu (703-605-0653 or via email Akinlosotu.bonaventure@epa.gov).

Sincerely,


Richard Gebken,
Product Manager 10
Insecticide Branch
Registration Division (7505P)

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels. The CRP required text will not change.]

Sergeant's Fipronil + Methoprene Squeeze-On for Dogs

[ABNs] [(Sergeant's®) (Sentry®) FRONTIER GOLD (Spot On) for dogs]

[ABNs] [(Sergeant's®) (Sentry®) Ectoadvance (Spot On) for dogs]

[ABNs] [SentryProline (Spot On) for dogs]

[ABNs] [[SENTRY®] FIPROGUARD™ PLUS for dogs]

[ABNs] [[Sergeant's®] PRONYL OTC™ PLUS for dogs]

[ABNs] [[Sergeant's®] [SENTRY®] AdvanSpot Plus (Spot On) for dogs]

[Apply to puppies over 8 weeks old]

[Apply to puppies 8 weeks or older]

ACCEPTED

FEB 21 2012

Under the Federal Insecticide, Fungicide
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA Reg. No.:

2517-134



[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Rapid elimination of chewing lice infestation]

[[A once monthly application required][Apply monthly to control] [for] chewing lice]

[Adult Fleas]

[[Kills [adult] Fleas [for up to three months]]

[Kills newly emerged adult Fleas before they lay eggs]

[Kills Adult Fleas, which may be a source of [flea allergy dermatitis] [, flea bite anemia]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If dog is a high risk for flea reinfestation a once month application may be needed]

[Multiple Infestations]

[Kills chewing lice [and controls mites that may cause sarcoptic mange]]

[Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 8 weeks old [&] [and] older]

[Kills fleas, flea eggs, ticks, chewing lice [&] [and] [mosquitoes]]

[Kills fleas, ticks, [mosquitoes], chewing lice, flea eggs, flea larvae [&] [and] [prevents the development of flea pupae]]

[Kills Fleas, Ticks [&] [and] [Mosquitoes]]

[Breaks the Flea Life Cycle [for up to three months]]

[Monthly flea, tick, [mosquito], chewing lice and flea egg protection]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Kills fleas, ticks, [mosquitoes], flea eggs, and chewing lice]

[[Seven] [7] [Six] [6] [Five] [5] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes],
chewing lice, flea eggs, [&] [and] flea larvae [&] [and] prevent the development of flea pupae]]

[[Six] [6] [Five] [5] [Four] [4] Way [Action] [Effectiveness] [Control] to kill fleas, ticks, [mosquitoes],
chewing lice, [&] [and] flea eggs [&] [and] flea larvae]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [30 day] [Flea, Tick, and Chewing Lice Control]

[[Four [4] Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Use [Full or Partial Brand Name] monthly to break the flea life cycle.]

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[Use **[Full or Partial Brand Name]** monthly to control ticks and chewing lice]
[Monthly flea, tick, [mosquito,] flea egg, flea larvae and chewing lice protection.]
[Once A Month Flea, Tick, [Mosquitoes] [and] [Chewing Lice][Application] [Treatment]]
[Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!]
[Kills Fleas, [and] [&] Ticks [and Mosquitoes] for up to [4 weeks] [1 month]!]
[Kills Fleas, Ticks, Flea Eggs [and] [&] Flea Larvae for up to [4 Weeks] [1 month] [30 days]]

[Ticks]

[Kills Ticks including those that may transmit Lyme disease]
[Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
[Kills [all stages of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]
[Kills Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
[Kills [brown dog ticks], [(*Rhipicephalus sanguineus*)] [American dog ticks,] [and] [lone star ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]
[Kills American Dog Ticks [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[Flea Eggs and Larvae]

[Controls flea reinfestation for up to [12 weeks] [3 months]]
[Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae for up to [three months] [12 weeks].]
[Effectively controls all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[Effective against all stages of the flea (including adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)]
[If dog is a high risk for flea reinfestation a once month application may be needed]
[Prevents from developing, flea eggs [larvae] [pupae] for up to [3 months] [12 weeks]]
[With (S)-methoprene Insect Growth Regulator [IGR] which Breaks the Flea Life Cycle]
[With (S)-methoprene to Break Flea Life Cycle]
[With Insect Growth Regulator [IGR] to Break Flea Life Cycle]
[Dual Action [!]: Fipronil with (S)-methoprene IGR [insect growth regulator] Effectively Breaks the Flea Life Cycle]
[Dual Action [!]: Effectively Breaks the Flea Life Cycle [!]]
[Kills Flea Eggs & Flea Larvae for [up to 3 months] [up to 12 weeks]!]
[Prevents Flea Eggs From Developing Into Biting Adults]
[Prevents all stages of the flea life cycle from developing]
[Controls reinfestation of fleas for up to 3 months]
[Effective against all stages of the flea life cycle]
[Effectively controls all stages of the flea life cycle]

[All Others]

[For Dogs and Puppies 8 weeks of age or older]
[Can be used on puppies 8 weeks of age and older]
[Specially Formulated for Dogs and Puppies 8 weeks of age or older]
[For Dogs [up to 22 lbs.], [23-44 lbs.], [45-88 lbs.], [89-132 lbs.]]
[Fast Acting] [Long Lasting]
[Convenient spot treatment]
[Easy to Use [Application]]
[Best if used year round!]

Sergeant's Master Label

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Information in [] is optional.

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FRONT PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[For year-round protection, apply **[Full or Partial Brand Name]** monthly]
[(ICON Showing [4 week] [1 month] [30 day] Protection)]
[Apply monthly]
[Prevents reinfestation of listed pests for [4 weeks] [1 month]]
[Apply once every [4 weeks] [month] [30 days]!]
[4 Week Dose!] [1 Month Dose!] [30 Day Dose!]
[One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][12 Applications][24 Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5 Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]
[Controls mites that may cause sarcoptic mange]
[Waterproof]
[Effective after bathing and exposure to water and sunlight]
[Can be used on breeding, pregnant, and lactating [bitches] [female] [dogs]]
[[Free] Calendar Stickers Inside!]
[[Free with purchase] [Free inside] Monthly Application Reminder [Magnet][inside]]
[Fipronil (9.8%) + (S)-methoprene (8.8%)]
[Contains Fipronil and (S)-methoprene[,] [-] the [same] active ingredients used in Frontline Plus® for dogs*]
[***[Full or Partial Brand Name]** is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.]
[Full or Partial Brand Name] is a registered trademark of Sergeant's Pet Care Products, Inc.]
[[1][2][3][4][5][6][12][24] Applications]
[Stops and prevents infestation of listed pests for [4 weeks][1 month]]
[Stops existing infestation and prevents establishment of additional infestation of listed pests]
[Lift [here] for more information]

[For use ONLY on dogs [&] [and] puppies]	[For Dogs & Puppies 8 weeks or older and]
[Up to 22 lbs.]	[up to 22 lbs.]
[23[-] [to] 44 lbs]	[For Dogs 23[-] [to] 44 lbs.]
[45[-] [to] 88 lbs]	[For Dogs 45[-] [to] 88 lbs.]
[89[-] [to] 132 lbs]	[For Dogs 89[-] [to] 132 lbs.]
[over 8 weeks of age]]	

ACTIVE INGREDIENTS:

Fipronil 9.80%
(S)-methoprene 8.80%

OTHER INGREDIENT:..... 81.40%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back][or][Side] [Label Panel[s]] for Additional Precautionary Statements

Net Contents: [1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.023 fl oz (0.67 ml) applicators
[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.045 fl oz (1.34 ml) applicators

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[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.091 fl oz (2.68 ml) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four]
0.136 fl oz (4.02 ml) applicators

{END - FRONT PANEL}

BACK /SIDE PANEL

DOG SQUEEZE ON FIPRONIL+METHOPRENE

[[Full or Partial Brand Name] contains Fipronil and S-Methoprene (insect growth regulator) (IGR) to effectively kill fleas and ticks [(including those that may transmit Lyme disease).] [The active ingredients in [Full or Partial Brand Name] feature a sustained release formula developed for fast acting [and long lasting] control of fleas, ticks, [mosquitoes] and chewing lice for up to [1 month] [[4][four] weeks] on dogs.]



READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged dogs. Call 1-800-781-4738 for 24-hour assistance.

FIRST AID

If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Flush eyes with plenty of water. Call a doctor if irritation persists.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

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BACK /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

Do not use on puppies under 8 weeks of age. Use entire contents of tube [vial] on each dog. [Do not split one tube between dogs.] [Do not use multiple tubes on one dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Can be used on breeding, pregnant, or lactating dogs. Consult a veterinarian before using on dogs with known organ dysfunction. Dogs may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. Sensitivities may occur after using ANY pesticide product on dogs. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

{Outer Packaging}

How to open: Remove product tubes [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the lines.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Do not apply more often than once every 4 weeks.

[Optional drawings that may or may not appear anywhere on finished label]



For Dogs Weighing up to 22 lbs. [including small dogs and puppies, 8 weeks or older]:

{For cartons containing 0.67 mL (0.023 fl oz) applicator tubes}

Apply one tube (0.67 mL)(0.023 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

For Dogs Weighing 23 [-] [to] 44 lbs.:

{For cartons containing 1.34 mL (0.045 fl oz) applicator tube}

Apply one tube (1.34 mL)(0.045 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

For Dogs Weighing 45 [-] [to] 88 lbs.:

{For cartons containing 2.68 mL (0.091 fl oz) applicator tube}

Apply one tube (2.68 mL)(0.091 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

Sergeant's Master Label

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BACK /SIDE PANEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

For Dogs Weighing 89 [-] [to] 132 lbs.:

{For cartons containing 4.02 mL (0.136 fl oz) applicator tube}

Apply one tube (4.02 mL)(0.136 fl oz) [from the back of the neck to a point midway between the neck and tail.] [as a spot [on] [to] the dog's back between the shoulder blades.]

FREQUENCY OF APPLICATION

Use [**Full or Partial Brand Name**] monthly for complete control of flea, tick, [and] chewing lice, [and mosquito] infestations. [Studies show that] [**Full or Partial Brand Name**] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation [, or in a highly infested environment]. Apply monthly to control ticks[,] [mosquitoes] and chewing lice. [**Full or Partial Brand Name**] [This product] remains effective even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F [/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

CONTAINER DISPOSAL: **If empty:** Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[**WARRANTY** Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Coupon(s) inside or on outside of box]
[Made in USA] [U.S. Patent No. 5,567,429]

Distributed by:
Sergeant's Pet Care Products, Inc.
P.O. Box 540399
Omaha, NE 68154-0399

[BAR CODE AREA][Lot code]
EPA Reg. No. 2517-134
EPA Est. No. 2517-TN-1 [XXX-XX-XXX]

{END - BACK / SIDE PANEL}

Sergeant's Master Label

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Information in [] is optional.

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

[Application Instructions] [Directions for Use]

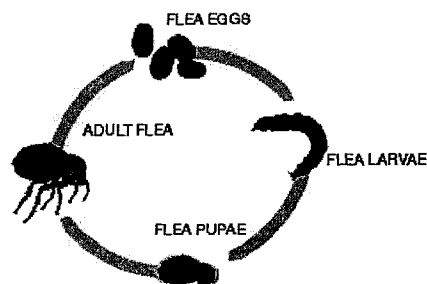
How to Open

1. Remove product tubes [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

[Optional drawings that may or may not appear anywhere on finished label]



[Flea life cycle diagram] [Flea Life Cycle]

[Sample coloring and layout may be different on final label]

[Look at the Label (Look at the Label icon) [Easy]

6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist]

- [1] Read the label completely and follow directions
- [2] Weigh your pet
- [3] Do NOT use dog products on cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the ENTIRE tube contents]

Sergeant's Master Label

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Information in [] is optional.

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OUTER PACKAGING OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

[Full or Partial Brand Name]

[1][2][3][4][5][6][12][24][Month [Application] Tracker]

[For year-round protection, apply [Full or Partial Brand Name] monthly.]

[Pet's Name (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[calendar stickers with Full or Partial Brand Name] [Place stickers on your calendar as a reminder to reapply [Full or Partial Brand Name] in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Full or Partial Brand Name]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Optional graphics below may or may not appear anywhere on finished label]



fleas



flea eggs



flea pupae



flea larvae



Adult Flea



ticks



Deer Tick



Brown Dog Tick



Lone Star Tick



American Dog Tick



chewing lice



mosquitoes



fleas



flea eggs



flea pupae



flea larvae



Adult Flea



ticks



Deer Tick



Brown Dog Tick



Lone Star Tick



American Dog Tick



chewing lice



mosquitoes

{END - PACKAGE COPY}

TUBE/VIAL LABEL

**DOG SQUEEZE ON
FIPRONIL+METHOPRENE**

{Front Label}

{Back Label}

{Brand Name}[cat graphic with line through]
For dogs [up to X][X-Y] lbs
Fipronil 9.8% w/w, (S)-methoprene 8.8% w/w
0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)
0.136 fl oz {label code}

KEEP OUT OF REACH OF CHILDREN
CAUTION: Read directions and precautions before
using. Use scissors to open.
EPA REG. No. 2517-134 {label code}

FOR OFFICIAL USE ONLY

FILE SYMBOL

2517-RGU

REGISTRATION NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
12/22/09		

**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

